

US3472020 (Prod: Penn Prevention - (CRS))

Generated By: KC Joubran

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US3472020

Form: Participant Creation

Data signed: (b) (4) 29 Mar 2021 15:38:10

Generated On: 11 Aug 2021 22:45:01

[Participant ID](#)

US3472020

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

US3472020

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 29 Mar 2021 15:38:51

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: Screening

Form: Demographics

Data signed: (b) (4) 29 Mar 2021 15:38:13

Generated On: 11 Aug 2021 22:45:01

Date of Birth (MMM yyyy)	(b) (6) 1964
Age	55
Age Units	YEARS
Age (Derived)	55
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 29 Mar 2021 15:38:13

Generated On: 11 Aug 2021 22:45:01

Date of Informed Consent (*dd MMM yyyy*) 08 SEP 2020

Month and Year of Informed Consent (derived) SEP 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1

Amendment 2

Amendment 3

Amendment 4

Amendment 5

Was participant enrolled in the study? Yes
No

If No, indicate reason for screen fail

Withdrew Consent

Inclusion/Exclusion

Cohort Full

Other

If reason for screen fail is Other, specify _____

Was this participant screened previously? Yes
No

If Yes, previous participant number _____

Enrollment Trigger 1

US3472020

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 29 Mar 2021 15:38:13

Generated On: 11 Aug 2021 22:45:01

Did the participant meet all eligibility criteria?

Yes

No

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 29 Mar 2021 15:38:14

Generated On: 11 Aug 2021 22:45:01

Were any significant conditions reported?

Yes

No

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 29 Mar 2021 15:38:13

Generated On: 11 Aug 2021 22:45:01

Condition	DISSECTED R CAROTID
Start date (dd MMM yyyy)	UN NOV 2006
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN OCT 2007
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2006
Start Year (derived)	2006
Stop Month and Year (derived)	OCT 2007
Stop Year (derived)	2007

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 29 Mar 2021 15:38:13

Generated On: 11 Aug 2021 22:45:01

Condition	MOOD DISORDER
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 29 Mar 2021 15:38:13

Generated On: 11 Aug 2021 22:45:01

Condition	HEP C+
Start date (dd MMM yyyy)	UN JAN 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN FEB 2017
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	FEB 2017
Stop Year (derived)	2017

US3472020

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 29 Mar 2021 15:38:13

Generated On: 11 Aug 2021 22:45:01

Condition	BASAL CELL CARCINOMA (SKIN)
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 29 Mar 2021 15:38:51

Generated On: 11 Aug 2021 22:45:01

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	8 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	11:16 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 11:16
Height (<i>xxx.x</i>)	68.5 in
Weight (<i>xxx.x</i>)	106.6 kg
BMI (<i>xxx.x</i>)	35.21345 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 29 Mar 2021 15:38:14

Generated On: 11 Aug 2021 22:45:01

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

8 SEP 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 29 Mar 2021 15:38:13

Generated On: 11 Aug 2021 22:45:01

Date of assessment (*dd MMM yyyy*) 8 SEP 2020

Is the participant of childbearing potential? Yes
No

If No, what is the reason? Surgically sterile
Post-menopausal
Partner medically sterile
Not reached age of Menarche
Other

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (*dd MMM yyyy*) _____

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) UN UNK 2016

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 29 Mar 2021 15:38:14

Generated On: 11 Aug 2021 22:45:01

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

WORKS WITH A HOME HEALTH AGENCY. DOES NOT INTERACT WITH PATIENTS.

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) 29 Mar 2021 15:38:14

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 29 Mar 2021 15:38:51

Generated On: 11 Aug 2021 22:45:01

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3472020

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 29 Mar 2021 15:38:51

Generated On: 11 Aug 2021 22:45:01

What was the date of randomization? (dd MMM yyyy) 08 SEP 2020

What was the participant's randomization number? 112014

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 15:38:51

Generated On: 11 Aug 2021 22:45:01

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 15:38:51

Generated On: 11 Aug 2021 22:45:01

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 (<i>dd MMM yyyy</i>)	8 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	11:16 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 11:16
Temperature (<i>xxx.x</i>)	36.2 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	67 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	66 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 15:38:51

Generated On: 11 Aug 2021 22:45:01

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 (<i>dd MMM yyyy</i>)	8 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	14:42 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 14:42
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>)	74 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	60 mmHg
Diastolic Blood Pressure units	MMHG

US3472020

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 29 Mar 2021 15:38:51

Generated On: 11 Aug 2021 22:45:01

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.

US3472020

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 29 Mar 2021 15:38:51

Generated On: 11 Aug 2021 22:45:01

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) 08 SEP 2020

What was the treatment time? (00:00-23:59) 14:10 (24 HR)

Treatment Date and Time (derived) 08 SEP 2020 14:10

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 15:38:51

Generated On: 11 Aug 2021 22:45:01

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	8 SEP 2020
Collection time (<i>00:00-23:59</i>)	13:17 (24 HR)
Collection date and time (derived)	8 SEP 2020 13:17

US3472020

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 29 Mar 2021 15:38:51

Generated On: 11 Aug 2021 22:45:01

Collection date (<i>dd MMM yyyy</i>)			8 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:50	8 SEP 2020 12:50
Nasopharyngeal Swab 2	No		

US3472020

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 15:38:51

Generated On: 11 Aug 2021 22:45:01

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 22:45:01

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 98.2 °F

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

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

PC Time Stamp 08 SEP 2020 14:44

PC Open Date & Time 08 SEP 2020 14:30

PC Close Date & Time 08 SEP 2020 17:00

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

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

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

08 SEP 2020 17:55

PC Close Date & Time

09 SEP 2020 11:59

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:45:01

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.0 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	09 SEP 2020 19:21
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:45:01

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.4 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	10 SEP 2020 18:58
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:45:01

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.1 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	11 SEP 2020 21:48
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:45:01

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.6 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	12 SEP 2020 20:23
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:45:01

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	96.6 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	13 SEP 2020 21:34
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:45:01

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.6 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	14 SEP 2020 20:36
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

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

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity
- Any use of prescription pain
reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**
Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity
- Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

08 SEP 2020 14:46

PC Open Date & Time

08 SEP 2020 14:30

PC Close Date & Time

08 SEP 2020 17:00

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

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)**

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

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

- Yes
- No

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

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

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

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

PC Open Date & Time

08 SEP 2020 17:55

PC Close Date & Time

09 SEP 2020 11:59

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

DAY 2

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	09 SEP 2020 19:22
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:45:01

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

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	10 SEP 2020 18:59
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

DAY 4

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

11 SEP 2020 21:49

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

DAY 5

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

12 SEP 2020 20:24

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

DAY 6

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

13 SEP 2020 21:35

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

DAY 7

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

14 SEP 2020 20:37

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:45:01

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

No

Yes

PC Time stamp	08 SEP 2020 14:47
PC Open Date & Time	08 SEP 2020 14:30
PC Close Date & Time	08 SEP 2020 17:00

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

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

No

Yes

PC Time stamp	09 SEP 2020 09:32
PC Open Date & Time	08 SEP 2020 17:55
PC Close Date & Time	09 SEP 2020 11:59

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:45:01

	Yes <input type="checkbox"/>
PC Time stamp	09 SEP 2020 19:23
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:45:01

	Yes <input type="checkbox"/>
PC Time stamp	10 SEP 2020 19:00
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:45:01

	Yes <input type="checkbox"/>
PC Time stamp	11 SEP 2020 21:49
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:45:01

	Yes <input type="checkbox"/>
PC Time stamp	12 SEP 2020 20:24
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:45:01

	Yes <input type="checkbox"/>
PC Time stamp	13 SEP 2020 21:35
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:45:01

Yes

PC Time stamp	14 SEP 2020 20:37
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3472020

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

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

PC Time Stamp 16 SEP 2020 10:41

PC Open Date & Time 15 SEP 2020 12:00

PC Close Date & Time 16 SEP 2020 11:59

US3472020

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None

HEADACHE

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

PC Time Stamp 16 SEP 2020 22:51

PC Open Date & Time 16 SEP 2020 12:00

PC Close Date & Time 17 SEP 2020 11:59

US3472020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:45:01

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	16 SEP 2020 10:41
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3472020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	16 SEP 2020 22:51
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3472020

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 15:38:13

Generated On: 11 Aug 2021 22:45:01

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 15 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3472020

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 15:38:13

Generated On: 11 Aug 2021 22:45:01

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3472020

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 15:38:13

Generated On: 11 Aug 2021 22:45:01

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 22 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3472020

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 15:38:13

Generated On: 11 Aug 2021 22:45:01

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3472020

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 15:38:13

Generated On: 11 Aug 2021 22:45:01

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 30 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3472020

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 15:38:13

Generated On: 11 Aug 2021 22:45:01

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3472020

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 29 Mar 2021 15:38:51

Generated On: 11 Aug 2021 22:45:01

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	7 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3472020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 29 Mar 2021 15:38:51

Generated On: 11 Aug 2021 22:45:01

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 (<i>dd MMM yyyy</i>)	7 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	11:24 (24 HR)
Vital Signs Date and Time (derived)	7 OCT 2020 11:24
Temperature (<i>xxx.x</i>)	36.3 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	71 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3472020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 29 Mar 2021 15:38:51

Generated On: 11 Aug 2021 22:45:01

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 (<i>dd MMM yyyy</i>)	7 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	12:34 (24 HR)
Vital Signs Date and Time (derived)	7 OCT 2020 12:34
Temperature (<i>xxx.x</i>)	36.4 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	63 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	105 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3472020

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Mar 2021 15:38:51

Generated On: 11 Aug 2021 22:45:01

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

7 OCT 2020

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

US3472020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 29 Mar 2021 15:38:51

Generated On: 11 Aug 2021 22:45:01

Was study treatment given? Yes
No

If No, reason not given

Participant declined due to Adverse Event
Physician withheld dose due to Adverse Event
Death
Lost To Follow-Up
Physician Decision
Pregnancy
Protocol Deviation
Study Terminated by Sponsor
Withdrawal of Consent by Participant
Confirmed COVID-19
Other

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 7 OCT 2020

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

Treatment Date and Time (derived) 7 OCT 2020 12:00

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

US3472020

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Mar 2021 15:38:51

Generated On: 11 Aug 2021 22:45:01

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	7 OCT 2020
Collection time (<i>00:00-23:59</i>)	11:30 (24 HR)
Collection date and time (derived)	7 OCT 2020 11:30

US3472020

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 29 Mar 2021 15:38:51

Generated On: 11 Aug 2021 22:45:01

Collection date (<i>dd MMM yyyy</i>)			7 OCT 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:35	7 OCT 2020 11:35
Nasopharyngeal Swab 2	No		

US3472020

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 15:38:51

Generated On: 11 Aug 2021 22:45:01

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:45:01

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 97.5 °F

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

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

PC Time Stamp 07 OCT 2020 12:24
PC Open Date & Time 07 OCT 2020 12:20
PC Close Date & Time 07 OCT 2020 14:50

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 97.9 °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 07 OCT 2020 19:45
PC Open Date & Time 07 OCT 2020 15:45
PC Close Date & Time 08 OCT 2020 11:59

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:45:01

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** 97.9 °F

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

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

PC Time Stamp 08 OCT 2020 19:36

PC Open Date & Time 08 OCT 2020 12:00

PC Close Date & Time 09 OCT 2020 11:59

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:45:01

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.9 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	09 OCT 2020 18:56
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:45:01

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.0 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	10 OCT 2020 20:33
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:45:01

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** 98.6 °F

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

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

PC Time Stamp	11 OCT 2020 18:22
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:45:01

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.0 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	12 OCT 2020 21:42
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:45:01

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

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

Yes

No

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

PC Time Stamp 14 OCT 2020 10:14

PC Open Date & Time 13 OCT 2020 12:00

PC Close Date & Time 14 OCT 2020 11:59

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

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

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity
- Any use of prescription pain
reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**
Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity
- Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp	07 OCT 2020 12:25
PC Open Date & Time	07 OCT 2020 12:20
PC Close Date & Time	07 OCT 2020 14:50

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

07 OCT 2020 19:46

PC Open Date & Time

07 OCT 2020 15:45

PC Close Date & Time

08 OCT 2020 11:59

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

DAY 2

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	08 OCT 2020 19:38
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:45:01

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

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

09 OCT 2020 18:57

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

DAY 4

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	10 OCT 2020 20:33
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

DAY 5

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	11 OCT 2020 18:22
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

DAY 6

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

12 OCT 2020 21:42

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

DAY 7

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	14 OCT 2020 10:15
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:45:01

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

No

Yes

PC Time stamp	07 OCT 2020 12:26
PC Open Date & Time	07 OCT 2020 12:20
PC Close Date & Time	07 OCT 2020 14:50

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

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

No

Yes

PC Time stamp	07 OCT 2020 19:47
PC Open Date & Time	07 OCT 2020 15:45
PC Close Date & Time	08 OCT 2020 11:59

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:45:01

	Yes <input type="checkbox"/>
PC Time stamp	08 OCT 2020 19:39
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:45:01

	Yes <input type="checkbox"/>
PC Time stamp	09 OCT 2020 18:57
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:45:01

	Yes <input type="checkbox"/>
PC Time stamp	10 OCT 2020 20:34
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:45:01

	Yes <input type="checkbox"/>
PC Time stamp	11 OCT 2020 18:23
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:45:01

	Yes <input type="checkbox"/>
PC Time stamp	12 OCT 2020 21:43
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:45:01

	Yes <input type="checkbox"/>
PC Time stamp	14 OCT 2020 10:15
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3472020

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 15:38:13

Generated On: 11 Aug 2021 22:45:01

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 14 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3472020

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 15:38:13

Generated On: 11 Aug 2021 22:45:01

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3472020

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 15:38:13

Generated On: 11 Aug 2021 22:45:01

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 21 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3472020

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 15:38:13

Generated On: 11 Aug 2021 22:45:01

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3472020

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 15:38:13

Generated On: 11 Aug 2021 22:45:01

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 31 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3472020

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 15:38:13

Generated On: 11 Aug 2021 22:45:01

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3472020

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 29 Mar 2021 15:38:51

Generated On: 11 Aug 2021 22:45:01

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 4 NOV 2020

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

Folder OID VISIT3

US3472020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Mar 2021 15:38:51

Generated On: 11 Aug 2021 22:45:01

Were vital signs assessed? Yes
No

Date of assessment (dd MMM yyyy) 04 NOV 2020

Time of assessment (00:00-23:59) 11:12 (24 HR)

Vital Signs Date and Time (derived) 04 NOV 2020 11:12

Temperature (xxx.x) 36.9 C

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (xxx) 79 beats/min

Pulse units BPM

Respiratory Rate (xxx) 16 breaths/min

Respiratory Rate units BREATHS/MIN

Systolic Blood Pressure (xxx) 112 mmHg

Systolic Blood Pressure units MMHG

Diastolic Blood Pressure (xxx) 79 mmHg

Diastolic Blood Pressure units MMHG

Height (derived) _____

Weight (derived) _____

US3472020

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Mar 2021 15:38:51

Generated On: 11 Aug 2021 22:45:01

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

04 NOV 2020

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

US3472020

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Mar 2021 15:38:51

Generated On: 11 Aug 2021 22:45:01

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 04 NOV 2020

Collection time (*00:00-23:59*) 11:55 (24 HR)

Collection date and time (derived) 04 NOV 2020 11:55

US3472020

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 15:38:51

Generated On: 11 Aug 2021 22:45:01

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3472020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

DAY 64

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

No

Yes

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

No

Yes

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

Date and time of submission 10 NOV 2020 08:29:08

Patient Cloud Open Date & Time 08 NOV 2020 00:01

Patient Cloud Close Date & Time 12 NOV 2020 23:59

US3472020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	15 NOV 2020 20:29:56
Patient Cloud Open Date & Time	15 NOV 2020 00:01
Patient Cloud Close Date & Time	19 NOV 2020 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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 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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2020 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Yes

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

No

Yes

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

Date and time of submission 27 NOV 2020 12:42:15

Patient Cloud Open Date & Time 26 NOV 2020 00:01

Patient Cloud Close Date & Time 30 NOV 2020 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" 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)	False
Chills	False
Cough	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	True
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	03 DEC 2020 16:14:57
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Yes

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

No

Yes

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

Date and time of submission 12 DEC 2020 15:51:26

Patient Cloud Open Date & Time 10 DEC 2020 00:01

Patient Cloud Close Date & Time 14 DEC 2020 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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 <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	20 DEC 2020 08:50:48
Patient Cloud Open Date & Time	17 DEC 2020 00:01
Patient Cloud Close Date & Time	21 DEC 2020 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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	24 DEC 2020 18:40:48
Patient Cloud Open Date & Time	24 DEC 2020 00:01
Patient Cloud Close Date & Time	28 DEC 2020 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2021 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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	08 JAN 2021 10:51:16
Patient Cloud Open Date & Time	07 JAN 2021 00:01
Patient Cloud Close Date & Time	11 JAN 2021 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Date and time of submission	
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" 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)	False
Chills	False
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	True
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	25 JAN 2021 12:09:21
Patient Cloud Open Date & Time	21 JAN 2021 00:01
Patient Cloud Close Date & Time	25 JAN 2021 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Date and time of submission	
Patient Cloud Open Date & Time	28 JAN 2021 00:01
Patient Cloud Close Date & Time	01 FEB 2021 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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 <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	04 FEB 2021 21:16:23
Patient Cloud Open Date & Time	04 FEB 2021 00:01
Patient Cloud Close Date & Time	08 FEB 2021 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

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

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

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

Date and time of submission 13 FEB 2021 16:24:54

Patient Cloud Open Date & Time 11 FEB 2021 00:01

Patient Cloud Close Date & Time 15 FEB 2021 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 FEB 2021 12:10:01
Patient Cloud Open Date & Time	18 FEB 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 FEB 2021 11:29:18
Patient Cloud Open Date & Time	25 FEB 2021 00:01
Patient Cloud Close Date & Time	01 MAR 2021 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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 08 MAR 2021 11:42:19

Patient Cloud Open Date & Time 04 MAR 2021 00:01

Patient Cloud Close Date & Time 08 MAR 2021 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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 11 MAR 2021 15:00:19

Patient Cloud Open Date & Time 11 MAR 2021 00:01

Patient Cloud Close Date & Time 15 MAR 2021 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

DAY 194

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

No

Yes

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

No

Yes

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

Date and time of submission 18 MAR 2021 08:53:20

Patient Cloud Open Date & Time 18 MAR 2021 00:01

Patient Cloud Close Date & Time 22 MAR 2021 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 MAR 2021 17:48:01
Patient Cloud Open Date & Time	25 MAR 2021 00:01
Patient Cloud Close Date & Time	29 MAR 2021 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

DAY 208

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

No

Yes

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

No

Yes

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

Date and time of submission 05 APR 2021 11:54:43

Patient Cloud Open Date & Time 01 APR 2021 00:01

Patient Cloud Close Date & Time 05 APR 2021 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 APR 2021 08:07:44
Patient Cloud Open Date & Time	08 APR 2021 00:01
Patient Cloud Close Date & Time	12 APR 2021 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

DAY 222

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

No

Yes

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

No

Yes

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

Date and time of submission 16 APR 2021 08:55:38

Patient Cloud Open Date & Time 15 APR 2021 00:01

Patient Cloud Close Date & Time 19 APR 2021 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

DAY 229

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

No

Yes

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

No

Yes

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

Date and time of submission 22 APR 2021 07:34:36

Patient Cloud Open Date & Time 22 APR 2021 00:01

Patient Cloud Close Date & Time 26 APR 2021 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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 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	29 APR 2021 08:29:10
Patient Cloud Open Date & Time	29 APR 2021 00:01
Patient Cloud Close Date & Time	03 MAY 2021 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

DAY 243

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

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

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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

DAY 250

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

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

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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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°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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Date and time of submission	
Patient Cloud Open Date & Time	20 MAY 2021 00:01
Patient Cloud Close Date & Time	24 MAY 2021 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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 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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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°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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2021 00:01
Patient Cloud Close Date & Time	07 JUN 2021 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

DAY 285

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Date and time of submission	
Patient Cloud Open Date & Time	17 JUN 2021 00:01
Patient Cloud Close Date & Time	21 JUN 2021 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Date and time of submission	
Patient Cloud Open Date & Time	24 JUN 2021 00:01
Patient Cloud Close Date & Time	28 JUN 2021 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

DAY 299

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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°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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Date and time of submission	
Patient Cloud Open Date & Time	15 JUL 2021 00:01
Patient Cloud Close Date & Time	19 JUL 2021 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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 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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

DAY 327

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Date and time of submission	
Patient Cloud Open Date & Time	29 JUL 2021 00:01
Patient Cloud Close Date & Time	02 AUG 2021 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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°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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01
Patient Cloud Close Date & Time	09 AUG 2021 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

DAY 341

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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 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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Date and time of submission	
Patient Cloud Open Date & Time	26 AUG 2021 00:01
Patient Cloud Close Date & Time	30 AUG 2021 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

DAY 369

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

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

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

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

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

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Date and time of submission	
Patient Cloud Open Date & Time	09 SEP 2021 00:01
Patient Cloud Close Date & Time	13 SEP 2021 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Date and time of submission	
Patient Cloud Open Date & Time	23 SEP 2021 00:01
Patient Cloud Close Date & Time	27 SEP 2021 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

DAY 390

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

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

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

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

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

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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°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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01
Patient Cloud Close Date & Time	18 OCT 2021 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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 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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2021 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

DAY 418

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Date and time of submission	
Patient Cloud Open Date & Time	28 OCT 2021 00:01
Patient Cloud Close Date & Time	01 NOV 2021 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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°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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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 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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Date and time of submission	
Patient Cloud Open Date & Time	18 NOV 2021 00:01
Patient Cloud Close Date & Time	22 NOV 2021 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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°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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Date and time of submission	
Patient Cloud Open Date & Time	25 NOV 2021 00:01
Patient Cloud Close Date & Time	29 NOV 2021 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 02 DEC 2021 00:01

[Patient Cloud Close Date & Time](#) 06 DEC 2021 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

DAY 460

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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 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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01
Patient Cloud Close Date & Time	20 DEC 2021 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

27 DEC 2021 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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°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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Date and time of submission

Patient Cloud Open Date & Time	30 DEC 2021 00:01
Patient Cloud Close Date & Time	03 JAN 2022 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

DAY 488

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

DAY 495

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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°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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 20 JAN 2022 00:01

[Patient Cloud Close Date & Time](#) 24 JAN 2022 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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°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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Date and time of submission	
Patient Cloud Open Date & Time	03 FEB 2022 00:01
Patient Cloud Close Date & Time	07 FEB 2022 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

DAY 530

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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°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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Date and time of submission

Patient Cloud Open Date & Time	24 FEB 2022 00:01
Patient Cloud Close Date & Time	28 FEB 2022 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

DAY 544

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#) 07 MAR 2022 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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°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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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°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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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°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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Date and time of submission	
Patient Cloud Open Date & Time	14 APR 2022 00:01
Patient Cloud Close Date & Time	18 APR 2022 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Date and time of submission	
Patient Cloud Open Date & Time	21 APR 2022 00:01
Patient Cloud Close Date & Time	25 APR 2022 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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 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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

DAY 607

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

DAY 614

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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 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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

[Patient Cloud Close Date & Time](#) 06 JUN 2022 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 23 JUN 2022 00:01

[Patient Cloud Close Date & Time](#) 27 JUN 2022 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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 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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

[Patient Cloud Close Date & Time](#)

25 JUL 2022 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

DAY 691

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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 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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Date and time of submission	
Patient Cloud Open Date & Time	18 AUG 2022 00:01
Patient Cloud Close Date & Time	22 AUG 2022 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

[Patient Cloud Close Date & Time](#)

29 AUG 2022 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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°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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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°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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2022 00:01
Patient Cloud Close Date & Time	12 SEP 2022 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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 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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

DAY 747

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

DAY 754

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

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

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

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

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

- Fever (Temperature \geq 100.4°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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

DAY 761

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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 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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

[Patient Cloud Close Date & Time](#) 17 OCT 2022 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2022 00:01
Patient Cloud Close Date & Time	24 OCT 2022 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

[Patient Cloud Close Date & Time](#)

31 OCT 2022 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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°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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

[Patient Cloud Close Date & Time](#)

07 NOV 2022 23:59

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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 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

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

[Patient Cloud Close Date & Time](#) 14 NOV 2022 23:59

US3472020

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:45:01

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		08 MAR 2021 11:42:30

US3472020

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 15:38:13

Generated On: 11 Aug 2021 22:45:01

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 30 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3472020

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 15:38:13

Generated On: 11 Aug 2021 22:45:01

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3472020

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 15:38:13

Generated On: 11 Aug 2021 22:45:01

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 02 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3472020

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 15:38:13

Generated On: 11 Aug 2021 22:45:01

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3472020

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 15:38:13

Generated On: 11 Aug 2021 22:45:01

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 03 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3472020

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 15:38:13

Generated On: 11 Aug 2021 22:45:01

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3472020

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 15:38:13

Generated On: 11 Aug 2021 22:45:01

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 3 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3472020

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 15:38:13

Generated On: 11 Aug 2021 22:45:01

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3472020

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 02 May 2021 18:58:26

Generated On: 11 Aug 2021 22:45:01

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 05 APR 2021

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

Folder OID VISIT4

US3472020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 May 2021 18:58:26

Generated On: 11 Aug 2021 22:45:01

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	05 APR 2021
Time of assessment (<i>00:00-23:59</i>)	11:43 (24 HR)
Vital Signs Date and Time (derived)	05 APR 2021 11:43
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>)	78 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	77 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3472020

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 02 May 2021 18:58:26

Generated On: 11 Aug 2021 22:45:01

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.

US3472020

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 May 2021 18:58:26

Generated On: 11 Aug 2021 22:45:01

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 05 APR 2021

Collection time (*00:00-23:59*) 11:45 (24 HR)

Collection date and time (derived) 05 APR 2021 11:45

US3472020

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 02 May 2021 18:58:11

Generated On: 11 Aug 2021 22:45:01

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3472020

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 02 May 2021 18:58:11

Generated On: 11 Aug 2021 22:45:01

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 2 MAY 2021

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

Comments

If Contact Not Made, please provide Comments

US3472020

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 02 May 2021 18:58:11

Generated On: 11 Aug 2021 22:45:01

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3472020

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:01

Was Contact Attempted? Yes
No

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

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

Comments _____

If Contact Not Made, please provide Comments _____

US3472020

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:01

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

Date of Contact	03 DEC 2020
Time of Contact	16:45
Date and Time of Contact (derived)	03 DEC 2020 16:45
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/> Clinical Visit - Unscheduled <input type="checkbox"/> Safety Call <input checked="" type="checkbox"/> Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

Symptom Day

Day 1	<input checked="" 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 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"/>

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

	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 DEC 2020
------	-------------

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

O2 Saturation	ND - Not Done
---------------	---------------

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

Temperature	ND - Not Done
-------------	---------------

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

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

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

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

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

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"/>

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

	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 DEC 2020
------	-------------

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

O2 Saturation	95 %
---------------	------

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

Temperature	99.8 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

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"/>

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

	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 DEC 2020
------	-------------

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

O2 Saturation	97 %
---------------	------

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

Temperature	97.0 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

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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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

	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 DEC 2020
------	-------------

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

O2 Saturation	98 %
---------------	------

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

Temperature	98.0 F
-------------	--------

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

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

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

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

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

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 03 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

Symptom Day

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

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

	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 DEC 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

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"/>

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

	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 DEC 2020

Assessment Not Done False

O2 Saturation 99 %

O2 Saturation Units %

Temperature 98.0 F

Chills

None

Mild

Moderate

Severe

Not Done

Cough

None

Mild

Moderate

Severe

Not Done

Shortness of Breath

None

Mild

Moderate

Severe

Not Done

Difficulty Breathing

None

Mild

Moderate

Severe

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

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"/>

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

	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 DEC 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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

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

PRODUCTION RELEASE (v12.003

353 of 3023

EAB) (1725)

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

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"/>

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

	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 DEC 2020
------	-------------

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

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

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

Temperature	97.6 F
-------------	--------

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

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

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

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

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

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

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

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 03 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

	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 DEC 2020
------	-------------

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

O2 Saturation	95 %
---------------	------

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

Temperature	99.1 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 type="checkbox"/>
	Mild	<input checked="" 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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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

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 03 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

	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 DEC 2020
------	-------------

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

O2 Saturation	98 %
---------------	------

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

Temperature	98.0 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 type="checkbox"/>
	Mild	<input checked="" 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

365 of 3023

EAB) (1725)

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

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 03 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

	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 DEC 2020
------	-------------

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

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

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

Temperature	98.0 F
-------------	--------

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

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

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

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

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

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"/>

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

	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 DEC 2020

Assessment Not Done False

O2 Saturation 99 %

O2 Saturation Units %

Temperature 97.0 F

Chills

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

Cough

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

Shortness of Breath

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

Difficulty Breathing

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

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"/>

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

	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 DEC 2020
------	-------------

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

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

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

Temperature	97.2 F
-------------	--------

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

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

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

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

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

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"/>

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

	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 DEC 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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

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

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

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"/>

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

	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 DEC 2020
------	-------------

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

O2 Saturation	98 %
---------------	------

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

Temperature	97.6 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

	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"/>

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

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"/>

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

	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 DEC 2020
------	-------------

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

O2 Saturation	97 %
---------------	------

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

Temperature	98.0 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

389 of 3023

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

Date of Visit 04 DEC 2020

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

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

Date of Test 04 DEC 2020

Type of Test Performed Nasopharyngeal Swab
Nasal Swab
Saliva Test
Other

Other, specify _____

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

If yes, provide lab information below

Lab/ Institution Test Performed _____

CLIA Certified? Yes
No

COVID-19 Positive (CSA Programming Field Only) 1

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

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

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

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

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

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

If Yes, provide:

Start Date _____

End Date _____

Oxygen Saturation _____

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

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes
No

Start Date _____

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

Start Date _____

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

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 _____

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

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 _____

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

[Generate Next COVID-19 Assessment](#)

Yes

No

US3472020

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 29 Mar 2021 15:38:12

Generated On: 11 Aug 2021 22:45:01

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	07 DEC 2020
Day 5	Yes	08 DEC 2020
Day 7	Yes	10 DEC 2020
Day 9	Yes	11 DEC 2020
Day 14	Yes	17 DEC 2020
Day 21	Yes	23 DEC 2020
Day 28	Yes	5 JAN 2021

US3472020

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 29 Mar 2021 15:38:12

Generated On: 11 Aug 2021 22:45:01

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 04 DEC 2020

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

Folder OID SICKD1

US3472020

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Mar 2021 15:38:12

Generated On: 11 Aug 2021 22:45:01

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	04 DEC 2020
Time of assessment (<i>00:00-23:59</i>)	14:29 (24 HR)
Vital Signs Date and Time (derived)	04 DEC 2020 14:29
Height (<i>xxx.x</i>)	ND - Not Done
Weight (<i>xxx.x</i>)	ND - Not Done
Temperature (<i>xxx.x</i>)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	74 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3472020

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Mar 2021 15:38:12

Generated On: 11 Aug 2021 22:45:01

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

04 DEC 2020

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

US3472020

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 29 Mar 2021 15:38:12

Generated On: 11 Aug 2021 22:45:01

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

Yes

No

NA (COVID-19 Negative)

Date of Collection

04 DEC 2020

US3472020

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3472020

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	5 JAN 2021
Time of assessment (<i>00:00-23:59</i>)	11:35 (24 HR)
Vital Signs Date and Time (derived)	5 JAN 2021 11:35
Height (<i>xxx.x</i>)	ND - Not Done
Weight (<i>xxx.x</i>)	ND - Not Done
Temperature (<i>xxx.x</i>)	36.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	68 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	72 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3472020

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

5 JAN 2021

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

US3472020

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 29 Mar 2021 15:38:11

Generated On: 11 Aug 2021 22:45:01

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

Yes

No

NA (COVID-19 Negative)

Date of Collection

5 JAN 2021

US3472020

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

Form: Visit Date

Data signed: (b) (4) 29 Mar 2021 15:38:13

Generated On: 11 Aug 2021 22:45:01

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	UNBLND_DECIDE

US3472020

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

Form: Unblinding

Data signed: (b) (4) 29 Mar 2021 15:38:13

Generated On: 11 Aug 2021 22:45:01

Date of updated informed consent (<i>dd MMM yyyy</i>)	4 FEB 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	4 FEB 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input 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

US3472020

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 29 Mar 2021 15:38:13

Generated On: 11 Aug 2021 22:45:01

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

US3472020

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 29 Mar 2021 15:38:13

Generated On: 11 Aug 2021 22:45:01

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	4 FEB 2021
Time of assessment (00:00-23:59)	12:04 (24 HR)
Vital Signs Date and Time (derived)	4 FEB 2021 12:04
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3472020

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 29 Mar 2021 15:38:13

Generated On: 11 Aug 2021 22:45:01

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)	04 FEB 2021
Time of assessment (00:00-23:59)	15:05 (24 HR)
Vital Signs Date and Time (derived)	04 FEB 2021 15:05
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3472020

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

Form: Physical Examination

Data signed: (b) (4) 29 Mar 2021 15:38:13

Generated On: 11 Aug 2021 22:45:01

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

04 FEB 2021

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

US3472020

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

Form: Exposure

Data signed: (b) (4) 29 Mar 2021 15:38:13

Generated On: 11 Aug 2021 22:45:01

Was study treatment given? Yes
No

If No, reason not given

Participant declined due to Adverse Event
Physician withheld dose due to Adverse Event
Death
Lost To Follow-Up
Physician Decision
Pregnancy
Protocol Deviation
Study Terminated by Sponsor
Withdrawal of Consent by Participant
Confirmed COVID-19
Other

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

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

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

What was the treatment time? (00:00-23:59) 14:35 (24 HR)

Treatment Date and Time (derived) 4 FEB 2021 14:35

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

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

US3472020

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Mar 2021 15:38:13

Generated On: 11 Aug 2021 22:45:01

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 4 FEB 2021

Collection time (*00:00-23:59*) 12:15 (24 HR)

Collection date and time (derived) 4 FEB 2021 12:15

US3472020

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 29 Mar 2021 15:38:13

Generated On: 11 Aug 2021 22:45:01

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 4 FEB 2021

Collection time (*00:00 - 23:59*) 12:10

Collection Date and Time (derived) 4 FEB 2021 12:10

US3472020

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

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 15:38:13

Generated On: 11 Aug 2021 22:45:01

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3472020

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 15:38:13

Generated On: 11 Aug 2021 22:45:01

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3472020

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 15:38:13

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 29 Mar 2021 15:38:12

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 29 Mar 2021 15:38:12

Generated On: 11 Aug 2021 22:45:01

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 (<i>dd MMM yyyy</i>)	4 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	11:30 (24 HR)
Vital Signs Date and Time (derived)	4 MAR 2021 11:30
Temperature (<i>xxx.x</i>)	36 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	71 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	64 mmHg
Diastolic Blood Pressure units	MMHG

US3472020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 29 Mar 2021 15:38:12

Generated On: 11 Aug 2021 22:45:01

Timepoint Pre-Dose
Post-Dose

Were vital signs assessed? Yes
No

Date of assessment (*dd MMM yyyy*) _____

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

Vital Signs Date and Time (derived) _____

Temperature (*xxx.x*) _____

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (*xxx*) _____

Pulse units _____

Respiratory Rate (*xxx*) _____

Respiratory Rate units _____

Systolic Blood Pressure (*xxx*) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (*xxx*) _____

Diastolic Blood Pressure units _____

US3472020

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Mar 2021 15:38:12

Generated On: 11 Aug 2021 22:45:01

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.

US3472020

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 29 Mar 2021 15:38:12

Generated On: 11 Aug 2021 22:45:01

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

STRONG REACTOGENICITY AFTER FIRST OPEN LABEL DOSE, SUSPECTED AS R/T PREVIOUS COVID-19 INFECTION, PT IMMUNITY LIKELY COMPARABLE TO THAT OF TWO-DOSE RECIPIENT.

What was the study treatment? (Unblinded) _____

What was the treatment date? (dd MMM yyyy) _____

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

Treatment Date and Time (derived) _____

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

What was the frequency of the study treatment dosing? _____

What was the route of administration for the study treatment? _____

US3472020

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 15:38:12

Generated On: 11 Aug 2021 22:45:01

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3472020

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 15:38:13

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 15:38:13

Generated On: 11 Aug 2021 22:45:01

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3472020

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 02 May 2021 18:58:11

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 02 May 2021 18:58:11

Generated On: 11 Aug 2021 22:45:01

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>)	11:43 (24 HR)
Vital Signs Date and Time (derived)	5 APR 2021 11:43
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>)	78 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	77 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3472020

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 02 May 2021 18:58:11

Generated On: 11 Aug 2021 22:45:01

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.

US3472020

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 May 2021 18:58:11

Generated On: 11 Aug 2021 22:45:01

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 5 APR 2021

Collection time (*00:00-23:59*) 11:45 (24 HR)

Collection date and time (derived) 5 APR 2021 11:45

US3472020

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 29 Mar 2021 15:38:10

Generated On: 11 Aug 2021 22:45:01

Did the participant experience any adverse events?

Yes

No

If Yes, enter details on the Adverse Events form.

US3472020

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Mar 2021 15:38:10

Generated On: 11 Aug 2021 22:45:01

AEID	
Adverse event	FATIGUE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	29 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	29 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

US3472020

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Mar 2021 15:38:10

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 29 Mar 2021 15:38:10

Generated On: 11 Aug 2021 22:45:01

AEID

Adverse event

GENERALIZED MYALGIA

Was this a medically-attended AE?

Yes

No

Was this a Solicited Adverse Reaction?

Yes

No

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes

No

Start date (dd MMM yyyy)

29 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes

No

If not Ongoing, end date (dd MMM yyyy)

29 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild

Grade 2/Moderate

Grade 3/Severe

Grade 4

Is the adverse event serious?

Yes

No

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes

No

Unknown

Number of Days in ICU

PRODUCTION RELEASE (v12.003

433 of 3023

EAB) (1725)

US3472020

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 29 Mar 2021 15:38:10

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 29 Mar 2021 15:38:10

Generated On: 11 Aug 2021 22:45:01

AEID	
Adverse event	DIARRHEA
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	18 OCT 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)	23 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

435 of 3023

US3472020

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 29 Mar 2021 15:38:10

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 29 Mar 2021 15:38:10

Generated On: 11 Aug 2021 22:45:01

AEID

Adverse event HEADACHE, INTERMITTENT

Was this a medically-attended AE? Yes
No

Was this a Solicited Adverse Reaction? Yes
No

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes
No

Start date (dd MMM yyyy) 08 SEP 2020

Start time (00:00-23:59) 21:00 (24 HR)

AE start date and time (derived) 08 SEP 2020 21:00

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy) 16 SEP 2020

End time (00:00-23:59) 10:00 (24 HR)

AE End Date and Time (derived) 16 SEP 2020 10:00

Severity Grade 1/Mild
Grade 2/Moderate
Grade 3/Severe
Grade 4

Is the adverse event serious? Yes
No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU? Yes
No
Unknown

Number of Days in ICU

US3472020

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 29 Mar 2021 15:38:10

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 29 Mar 2021 15:38:10

Generated On: 11 Aug 2021 22:45:01

AEID	
Adverse event	KNEE PAIN
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	21 OCT 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)	23 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 29 Mar 2021 15:38:10

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 29 Mar 2021 15:38:10

Generated On: 11 Aug 2021 22:45:01

AEID	
Adverse event	WET COUGH
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	3 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)	23 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 29 Mar 2021 15:38:10

Generated On: 11 Aug 2021 22:45:01

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

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Folder: Adverse Events

Form: Adverse Events (15)

Data signed: (b) (4) 29 Mar 2021 15:38:10

Generated On: 11 Aug 2021 22:45:01

AEID	USA-US122-2020-MRNA-1273-P30 1000005
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 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	18 DEC 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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Folder: Adverse Events

Form: Adverse Events (15)

Data signed: (b) (4) 29 Mar 2021 15:38:10

Generated On: 11 Aug 2021 22:45:01

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	ACETAMINOPHEN TAKEN FOR TREATMENT
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (16)

Data signed: (b) (4) 29 Mar 2021 15:38:10

Generated On: 11 Aug 2021 22:45:01

AEID	
Adverse event	SORE THROAT
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	18 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	20 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (16)

Data signed: (b) (4) 29 Mar 2021 15:38:10

Generated On: 11 Aug 2021 22:45:01

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

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Folder: Adverse Events

Form: Adverse Events (17)

Data signed: (b) (4) 29 Mar 2021 15:38:10

Generated On: 11 Aug 2021 22:45:01

AEID	
Adverse event	PAROTITIS
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	15 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (17)

Data signed: (b) (4) 29 Mar 2021 15:38:10

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 29 Mar 2021 15:38:10

Generated On: 11 Aug 2021 22:45:01

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

Yes

No

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 02 May 2021 18:58:10

Generated On: 11 Aug 2021 22:45:01

Name of Medication LEXAPRO

Prophylaxis Yes
No

Indication MOOD DISORDER

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 02 May 2021 18:58:10

Generated On: 11 Aug 2021 22:45:01

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 2017

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 02 May 2021 18:58:10

Generated On: 11 Aug 2021 22:45:01

Name of Medication MG CITRATE SUPPLEMENT

Prophylaxis Yes
No

Indication NUTRITIONAL SUPPORT

Dose per administration 200

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 02 May 2021 18:58:10

Generated On: 11 Aug 2021 22:45:01

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 28 AUG 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 02 May 2021 18:58:10

Generated On: 11 Aug 2021 22:45:01

Name of Medication MG GLYCINATE SUPPLEMENT

Prophylaxis Yes
No

Indication NUTRITIONAL SUPPORT

Dose per administration 200

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 02 May 2021 18:58:10

Generated On: 11 Aug 2021 22:45:01

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 28 AUG 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 02 May 2021 18:58:10

Generated On: 11 Aug 2021 22:45:01

Name of Medication INFLUENZA VACCINATION

Prophylaxis Yes
No

Indication INFLUENZA PROPHYLAXIS

Dose per administration 1

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify INJECTION

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 02 May 2021 18:58:10

Generated On: 11 Aug 2021 22:45:01

	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*) 10 NOV 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 10 NOV 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 02 May 2021 18:58:10

Generated On: 11 Aug 2021 22:45:01

Name of Medication ACETAMINOPHEN

Prophylaxis Yes
No

Indication COVID-19

Dose per administration 650

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 02 May 2021 18:58:10

Generated On: 11 Aug 2021 22:45:01

	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 DEC 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 18 DEC 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 02 May 2021 18:58:10

Generated On: 11 Aug 2021 22:45:01

Name of Medication LEXAPRO

Prophylaxis Yes
No

Indication MOOD DISORDER

Dose per administration 4

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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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 18:58:10

Generated On: 11 Aug 2021 22:45:01

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*) 2 JAN 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 02 May 2021 18:58:10

Generated On: 11 Aug 2021 22:45:01

Name of Medication NAPROXEN

Prophylaxis Yes
No

Indication FEVER

Dose per administration 1000

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 02 May 2021 18:58:10

Generated On: 11 Aug 2021 22:45:01

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 FEB 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 06 FEB 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 02 May 2021 18:58:10

Generated On: 11 Aug 2021 22:45:01

Name of Medication ACETAMINOPHEN

Prophylaxis Yes
No

Indication FEVER

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
EAB) (1725)

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US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 02 May 2021 18:58:10

Generated On: 11 Aug 2021 22:45:01

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 FEB 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 06 FEB 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 02 May 2021 18:58:10

Generated On: 11 Aug 2021 22:45:01

Name of Medication PREDNISONE

Prophylaxis Yes
No

Indication PAROTITIS

Dose per administration 40

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

466 of 3023

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 02 May 2021 18:58:10

Generated On: 11 Aug 2021 22:45:01

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*) 25 FEB 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 03 MAR 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 02 May 2021 18:58:10

Generated On: 11 Aug 2021 22:45:01

Name of Medication NYQUIL (NO FURTHER INFORMATION)

Prophylaxis Yes
No

Indication SORE THROAT

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)

468 of 3023

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 02 May 2021 18:58:10

Generated On: 11 Aug 2021 22:45:01

	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) 19 JAN 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 19 JAN 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 02 May 2021 18:58:10

Generated On: 11 Aug 2021 22:45:01

Name of Medication NYQUIL (NO FURTHER INFORMATION)

Prophylaxis Yes
No

Indication MALAISE

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)

470 of 3023

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 02 May 2021 18:58:10

Generated On: 11 Aug 2021 22:45:01

	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) 04 FEB 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 04 FEB 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 02 May 2021 18:58:10

Generated On: 11 Aug 2021 22:45:01

Name of Medication ACETAMINOPHEN

Prophylaxis Yes
No

Indication PAROTITIS

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
EAB) (1725)

472 of 3023

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 02 May 2021 18:58:10

Generated On: 11 Aug 2021 22:45:01

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*) 25 FEB 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 25 FEB 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 02 May 2021 18:58:10

Generated On: 11 Aug 2021 22:45:01

Name of Medication MELOXICAM

Prophylaxis Yes
No

Indication PAROTITIS

Dose per administration 15

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)

474 of 3023

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 02 May 2021 18:58:10

Generated On: 11 Aug 2021 22:45:01

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*) 16 MAR 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3472020

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 29 Mar 2021 15:38:10

Generated On: 11 Aug 2021 22:45:01

Were any concomitant procedures performed?

Yes

No

If yes, please complete Concomitant Procedures form.

US3472020

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:45:01

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

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form

Data signed: (b) (4) 29 Mar 2021 15:38:13

Generated On: 11 Aug 2021 22:45:01

SAEID	USA-US122-2020-MRNA-1273-P301000005
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)	4

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Data signed: (b) (4) 29 Mar 2021 15:38:13

Generated On: 11 Aug 2021 22:45:01

SAEID USA-US122-2020-MRNA-1273-P30
1000005

Serious Yes
No

Death Yes
No

Life threatening Yes
No

Requires inpatient or prolongation of existing Hospitalization Yes
No

Persistent or significant disability or incapacity Yes
No

Congenital anomaly or birth defect Yes
No

Other medically important event Yes
No

Investigator's First Name _____

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) 4

Date of submission (Pre-filled from custom function) 11/DEC/2020 16:17

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

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Data signed: (b) (4) 29 Mar 2021 15:38:13

Generated On: 11 Aug 2021 22:45:01

SAEID USA-US122-2020-MRNA-1273-P30
1000005

Serious Yes
No

Death Yes
No

Life threatening Yes
No

Requires inpatient or prolongation of existing Hospitalization Yes
No

Persistent or significant disability or incapacity Yes
No

Congenital anomaly or birth defect Yes
No

Other medically important event Yes
No

Investigator's First Name _____

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) 4

Date of submission (Pre-filled from custom function) 22/DEC/2020 16:03

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

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Data signed: (b) (4) 29 Mar 2021 15:38:13

Generated On: 11 Aug 2021 22:45:01

SAEID USA-US122-2020-MRNA-1273-P30
1000005

Serious Yes
No

Death Yes
No

Life threatening Yes
No

Requires inpatient or prolongation of existing Hospitalization Yes
No

Persistent or significant disability or incapacity Yes
No

Congenital anomaly or birth defect Yes
No

Other medically important event Yes
No

Investigator's First Name _____

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) 4

Date of submission (Pre-filled from custom function) 23/DEC/2020 15:36

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

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Data signed: (b) (4) 29 Mar 2021 15:38:13

Generated On: 11 Aug 2021 22:45:01

SAEID USA-US122-2020-MRNA-1273-P30
1000005

Serious Yes
No

Death Yes
No

Life threatening Yes
No

Requires inpatient or prolongation of existing Hospitalization Yes
No

Persistent or significant disability or incapacity Yes
No

Congenital anomaly or birth defect Yes
No

Other medically important event Yes
No

Investigator's First Name _____

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) 4

Date of submission (Pre-filled from custom function) 05/JAN/2021 10:19

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. True

Audit

US3472020 (Prod: Penn Prevention - (CRS))

US3472020

Form: Participant Creation

Generated On: 11 Aug 2021 22:45:01

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:15
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered 'US3472020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 15:10:06

US3472020

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:45:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:45:15
User entered 'Yes (Y)'	Juan Diego Ramirez (b) (4)	08 Sep 2020 18:17:06

US3472020

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:45:15
User entered '08 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 15:10:07

US3472020

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:45:01

[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 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:45:15
User entered 'Clinic (Clinic)'	Juan Diego Ramirez (b) (4)	08 Sep 2020 18:17:06

US3472020

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:45:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User entered 'SCRN'	System	08 Sep 2020 18:17:06

US3472020

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:45:01
User entered (b) (6) 1964'	RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 15:10:08

US3472020

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:45:01

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:45:01
User entered '55'	Jie Ho (b) (4)	08 Sep 2020 19:28:34

US3472020

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:45:01

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User entered 'YEARS'	System	08 Sep 2020 19:28:34

US3472020

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:45:01

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User entered '55'	System	08 Sep 2020 18:17:30

US3472020

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:45:01

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:45:01
User entered 'Female (F)'	Jie Ho (b) (4)	08 Sep 2020 19:28:34

US3472020

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:45:01

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:45:01
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Jie Ho (b) (4)	08 Sep 2020 19:28:34

US3472020

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:45:01

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:45:01
User entered '1'	Jie Ho (b) (4)	08 Sep 2020 19:28:34

US3472020

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:45:01

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:45:01
User entered '0'	Jie Ho (b) (4)	08 Sep 2020 19:28:34

US3472020

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:45:01

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:45:01
User entered '0'	Jie Ho (b) (4)	08 Sep 2020 19:28:34

US3472020

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:45:01

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:45:01
User entered '0'	Jie Ho (b) (4)	08 Sep 2020 19:28:34

US3472020

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:45:01

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:45:01
User entered '0'	Jie Ho (b) (4)	08 Sep 2020 19:28:34

US3472020

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:45:01

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:45:01
User entered '0'	Jie Ho (b) (4)	08 Sep 2020 19:28:34

US3472020

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:45:01

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:45:01
User entered empty.	Jie Ho (b) (4)	08 Sep 2020 19:28:34

US3472020

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:45:01

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:45:01
User entered '0'	Jie Ho (b) (4)	08 Sep 2020 19:28:34

US3472020

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:45:01

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:45:01
User entered '0'	Jie Ho (b) (4)	08 Sep 2020 19:28:34

US3472020

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:45:01

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:45:28
User entered '08 Sep 2020'	Juan Diego Ramirez (b) (4)	08 Sep 2020 18:17:30

US3472020

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User entered 'Sep 2020'	System	08 Sep 2020 18:17:30

US3472020

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User entered '2020'	System	08 Sep 2020 18:17:30

US3472020

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:45:01

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:45:28
User entered 'Amendment 3 (3)'	Juan Diego Ramirez (b) (4)	08 Sep 2020 18:17:30

US3472020

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:45:28
User entered 'Yes (Y)'	Juan Diego Ramirez (b) (4)	08 Sep 2020 18:17:30

US3472020

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:45:01

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:45:28
User entered empty.	Juan Diego Ramirez (b) (4)	08 Sep 2020 18:17:30

US3472020

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:45:01

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:45:28
User entered empty.	Juan Diego Ramirez (b) (4)	08 Sep 2020 18:17:30

US3472020

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:45:01

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:45:28
User entered 'No (N)'	Juan Diego Ramirez (b) (4)	08 Sep 2020 18:17:30

US3472020

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:45:01

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:45:28
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 15:10:07

US3472020

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:45:01

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User entered '1'	System	08 Sep 2020 18:17:39

US3472020

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 02:33:06
User entered 'Yes (Y)'	Juan Diego Ramirez (b) (4)	08 Sep 2020 18:17:39

US3472020

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:45:01

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:51:28
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 03:43:23
User entered 'No (N)'	(b) (4), (b) (6)	09 Sep 2020 02:42:32

US3472020

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:45:01

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:55:57
DataPoint Un-verified.	(b) (4), (b) (6)	16 Sep 2020 21:54:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 21:53:49
User coded data point as SOC: Nervous system disorders, HLG: Central nervous system vascular disorders, HLT: Central nervous system aneurysms and dissections, PT: Carotid artery dissection, LLT: Carotid artery dissection - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 14:08:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 14:08:55
Data point term sent to Coder	System	09 Sep 2020 03:45:18
User entered 'Dissected R carotid'	(b) (4), (b) (6)	09 Sep 2020 03:44:56

US3472020

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:55:57
DataPoint Un-verified.	(b) (4), (b) (6)	16 Sep 2020 21:54:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 21:53:49
User entered 'UN Nov 2006'	(b) (4), (b) (6)	09 Sep 2020 03:44:56

US3472020

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:45:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:55:57
DataPoint Un-verified.	(b) (4), (b) (6)	16 Sep 2020 21:54:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 21:53:49
User entered '0'	(b) (4), (b) (6)	09 Sep 2020 03:44:56

US3472020

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:45:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:55:57
DataPoint Un-verified.	(b) (4), (b) (6)	16 Sep 2020 21:54:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 21:53:49
User entered 'No (N)'	(b) (4), (b) (6)	09 Sep 2020 03:44:56

US3472020

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:55:57
DataPoint Un-verified.	(b) (4), (b) (6)	16 Sep 2020 21:54:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 21:53:49
User entered 'UN Oct 2007'	(b) (4), (b) (6)	09 Sep 2020 03:44:56

US3472020

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:45:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:55:57
DataPoint Un-verified.	(b) (4), (b) (6)	16 Sep 2020 21:54:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 21:53:49
User entered '0'	(b) (4), (b) (6)	09 Sep 2020 03:44:56

US3472020

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:45:01

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User entered 'Nov 2006'	System	09 Sep 2020 03:44:56

US3472020

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User entered '2006'	System	09 Sep 2020 03:44:56

US3472020

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User entered 'Oct 2007'	System	09 Sep 2020 03:44:56

US3472020

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User entered '2007'	System	09 Sep 2020 03:44:56

US3472020

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:45:01

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:55:57
DataPoint Un-verified.	(b) (4), (b) (6)	16 Sep 2020 21:54:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 21:53:49
User coded data point as SOC: Psychiatric disorders, HLT: Mood disorders and disturbances NEC, HLT: Mood disorders NEC, PT: Affective disorder, LLT: Mood disorder - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 03:47:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 03:47:43
Data point term sent to Coder	System	09 Sep 2020 03:46:19
User entered 'Mood disorder'	(b) (4), (b) (6)	09 Sep 2020 03:45:43

US3472020

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:45:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 19:27:28
User closed query 'Per source, year is recorded as 2017. Please confirm/correct. ' (Site from CRA).	(b) (4), (b) (6)	02 Nov 2020 19:24:14
Query 'Per source, year is recorded as 2017. Please confirm/correct. ' answered with 'Updated, thank you.' (Site from CRA).	Jie Ho (b) (4)	16 Sep 2020 23:09:49
User entered 'UN UNK 2017' reason for change: Data Entry Error	Jie Ho (b) (4)	16 Sep 2020 23:09:42
DataPoint Un-verified.	(b) (4), (b) (6)	16 Sep 2020 21:56:04
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 21:55:57
User opened query 'Per source, year is recorded as 2017. Please confirm/correct. ' (Site from CRA).	(b) (4), (b) (6)	16 Sep 2020 21:55:32
DataPoint Un-verified.	(b) (4), (b) (6)	16 Sep 2020 21:54:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 21:53:49
User entered 'UN UNK 2007'	(b) (4), (b) (6)	09 Sep 2020 03:45:43

US3472020

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:45:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4)	16 Sep 2020 21:55:57
DataPoint Un-verified.	(b) (4), (b) (6)	16 Sep 2020 21:54:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 21:53:49
User entered '0'	(b) (4), (b) (6)	09 Sep 2020 03:45:43

US3472020

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:45:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4)	16 Sep 2020 21:55:57
DataPoint Un-verified.	(b) (4), (b) (6)	16 Sep 2020 21:54:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 21:53:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Sep 2020 03:45:43

US3472020

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4)	16 Sep 2020 21:55:57
DataPoint Un-verified.	(b) (4), (b) (6)	16 Sep 2020 21:54:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 21:53:49
User entered empty.	(b) (4), (b) (6)	09 Sep 2020 03:45:43

US3472020

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:45:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4)	16 Sep 2020 21:55:57
DataPoint Un-verified.	(b) (4), (b) (6)	16 Sep 2020 21:54:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 21:53:49
User entered '0'	(b) (4), (b) (6)	09 Sep 2020 03:45:43

US3472020

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:45:01

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User entered 'Jan 2017'	System	16 Sep 2020 23:09:42
User entered 'Jan 2007'	System	09 Sep 2020 03:45:43

US3472020

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:45:01

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User entered '2017'	System	16 Sep 2020 23:09:42
User entered '2007'	System	09 Sep 2020 03:45:43

US3472020

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User entered empty.	System	09 Sep 2020 03:45:43

US3472020

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User entered empty.	System	09 Sep 2020 03:45:43

US3472020

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:45:01

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:55:57
DataPoint Un-verified.	(b) (4), (b) (6)	16 Sep 2020 21:54:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 21:53:49
User coded data point as SOC: Investigations, HLGTT: Microbiology and serology investigations, HLT: Virus identification and serology, PT: Hepatitis C virus test positive, LLT: Hepatitis C positive - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 09:06:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 09:06:40
Data point term sent to Coder	System	09 Sep 2020 03:48:20
User entered 'Hep C+'	(b) (4), (b) (6)	09 Sep 2020 03:48:14

US3472020

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4)	16 Sep 2020 21:55:57
DataPoint Un-verified.	(b) (4), (b) (6)	16 Sep 2020 21:54:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 21:53:49
User entered 'UN Jan 2017'	(b) (4), (b) (6)	09 Sep 2020 03:48:14

US3472020

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:45:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:55:57
DataPoint Un-verified.		16 Sep 2020 21:54:13
DataPoint Verified.		16 Sep 2020 21:53:49
User entered '0'		09 Sep 2020 03:48:14

US3472020

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:45:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:55:57
DataPoint Un-verified.		16 Sep 2020 21:54:13
DataPoint Verified.		16 Sep 2020 21:53:49
User entered 'No (N)'		09 Sep 2020 03:48:14

US3472020

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4)	16 Sep 2020 21:55:57
DataPoint Un-verified.	(b) (4), (b) (6)	16 Sep 2020 21:54:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 21:53:49
User entered 'UN Feb 2017'	(b) (4), (b) (6)	09 Sep 2020 03:48:14

US3472020

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:45:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:55:57
DataPoint Un-verified.		16 Sep 2020 21:54:13
DataPoint Verified.		16 Sep 2020 21:53:49
User entered '0'		09 Sep 2020 03:48:14

US3472020

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:45:01

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User entered 'Jan 2017'	System	09 Sep 2020 03:48:14

US3472020

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:45:01

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User entered '2017'	System	09 Sep 2020 03:48:14

US3472020

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User entered 'Feb 2017'	System	09 Sep 2020 03:48:14

US3472020

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User entered '2017'	System	09 Sep 2020 03:48:14

US3472020

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:45:01

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:55:57
DataPoint Un-verified.	(b) (4), (b) (6)	16 Sep 2020 21:54:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 21:53:49
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Skin neoplasms malignant and unspecified, HLT: Skin neoplasms malignant and unspecified (excl melanoma), PT: Basal cell carcinoma, LLT: Basal cell carcinoma - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 05:31:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 05:31:45
Data point term sent to Coder	System	09 Sep 2020 03:50:20
User entered 'Basal cell carcinoma (skin)'	(b) (4), (b) (6)	09 Sep 2020 03:49:37

US3472020

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4)	16 Sep 2020 21:55:57
DataPoint Un-verified.	(b) (4), (b) (6)	16 Sep 2020 21:54:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 21:53:49
User entered 'UN UNK 2010'	(b) (4), (b) (6)	09 Sep 2020 03:49:37

US3472020

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:45:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4)	16 Sep 2020 21:55:57
DataPoint Un-verified.	(b) (4), (b) (6)	16 Sep 2020 21:54:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 21:53:49
User entered '0'	(b) (4), (b) (6)	09 Sep 2020 03:49:37

US3472020

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:45:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4)	16 Sep 2020 21:55:57
DataPoint Un-verified.	(b) (4), (b) (6)	16 Sep 2020 21:54:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 21:53:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Sep 2020 03:49:37

US3472020

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4)	16 Sep 2020 21:55:57
DataPoint Un-verified.	(b) (4), (b) (6)	16 Sep 2020 21:54:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 21:53:49
User entered empty.	(b) (4), (b) (6)	09 Sep 2020 03:49:37

US3472020

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:45:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4)	16 Sep 2020 21:55:57
DataPoint Un-verified.	(b) (4), (b) (6)	16 Sep 2020 21:54:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 21:53:49
User entered '0'	(b) (4), (b) (6)	09 Sep 2020 03:49:37

US3472020

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:45:01

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User entered 'Jan 2010'	System	09 Sep 2020 03:49:37

US3472020

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:45:01

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User entered '2010'	System	09 Sep 2020 03:49:37

US3472020

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User entered empty.	System	09 Sep 2020 03:49:37

US3472020

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User entered empty.	System	09 Sep 2020 03:49:37

US3472020

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:58:47
User entered 'Yes (Y)'		09 Sep 2020 02:50:24

US3472020

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:58:47
User entered '8 Sep 2020'		09 Sep 2020 02:50:24

US3472020

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:58:47
User entered '11:16'		09 Sep 2020 02:50:24

US3472020

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User entered '8 Sep 2020 11:16'	System	09 Sep 2020 02:50:24

US3472020

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:58:47
User entered '68.5' in		09 Sep 2020 02:50:24
DataPoint set to visible.	System	08 Sep 2020 18:17:39

US3472020

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:58:47
User entered '106.6' kg	(b) (4)	09 Sep 2020 02:50:24
DataPoint set to visible.	System	08 Sep 2020 18:17:39

US3472020

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User entered '35.21345'	System	09 Sep 2020 02:50:24
DataPoint set to visible.	System	08 Sep 2020 18:17:39

US3472020

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User entered 'kg/m2'	System	09 Sep 2020 02:50:24
DataPoint set to visible.	System	08 Sep 2020 18:17:39

US3472020

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:58:47
User closed query 'Data is required. Please provide.' (Site from System).	System	09 Sep 2020 02:51:08
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	09 Sep 2020 02:51:08
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 02:51:08
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Sep 2020 02:50:24
User entered empty.	(b) (4), (b) (6)	09 Sep 2020 02:50:24

US3472020

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:58:47
User entered empty.		09 Sep 2020 02:50:24

US3472020

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:58:47
User entered empty.		09 Sep 2020 02:50:24

US3472020

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:58:47
User closed query 'Data is required. Please provide.' (Site from System).	System	09 Sep 2020 02:51:08
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	09 Sep 2020 02:51:08
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 02:51:08
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Sep 2020 02:50:24
User entered empty.	(b) (4), (b) (6)	09 Sep 2020 02:50:24

US3472020

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User entered 'bpm'	System	09 Sep 2020 02:51:08
User entered empty.	System	09 Sep 2020 02:50:24

US3472020

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:58:47
User closed query 'Data is required. Please provide.' (Site from System).	System	09 Sep 2020 02:51:08
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	09 Sep 2020 02:51:08
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 02:51:08
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Sep 2020 02:50:24
User entered empty.	(b) (4), (b) (6)	09 Sep 2020 02:50:24

US3472020

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User entered 'breaths/min'	System	09 Sep 2020 02:51:08
User entered empty.	System	09 Sep 2020 02:50:24

US3472020

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:58:47
User closed query 'Data is required. Please provide.' (Site from System).	System	09 Sep 2020 02:51:08
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	09 Sep 2020 02:51:08
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 02:51:08
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Sep 2020 02:50:24
User entered empty.	(b) (4), (b) (6)	09 Sep 2020 02:50:24

US3472020

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User entered 'mmHg'	System	09 Sep 2020 02:51:08
User entered empty.	System	09 Sep 2020 02:50:24

US3472020

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:58:47
User closed query 'Data is required. Please provide.' (Site from System).	System	09 Sep 2020 02:51:08
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	09 Sep 2020 02:51:08
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 02:51:08
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Sep 2020 02:50:24
User entered empty.	(b) (4), (b) (6)	09 Sep 2020 02:50:24

US3472020

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User entered 'mmHg'	System	09 Sep 2020 02:51:08
User entered empty.	System	09 Sep 2020 02:50:24

US3472020

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12

US3472020

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12

US3472020

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:45:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:58:56
User entered 'Yes (Y)'		09 Sep 2020 02:53:40

US3472020

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:45:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:58:56
User entered '8 Sep 2020'		09 Sep 2020 02:53:40

US3472020

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:45:01

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:59:03
User entered '8 Sep 2020'		09 Sep 2020 02:56:27

US3472020

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:45:01

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:59:03
User entered 'No (N)'		09 Sep 2020 02:56:27

US3472020

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:45:01

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 09:06:34
Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. answered with 'Per protocol only significant findings prior to signature of the informed consent are required to be included in the Medical History eCRF. This is not considered medically significant and thus not recorded.' (Site from DM).	Jie Ho (b) (4)	09 Oct 2020 18:24:13
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 05:21:09
DataPoint Verified.		16 Sep 2020 21:59:03
User entered 'Post-menopausal (POST-MENOPAUSAL)'		09 Sep 2020 02:56:27

US3472020

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:45:01

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:59:03
User entered empty.		09 Sep 2020 02:56:27

US3472020

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:45:01

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:59:03
User entered empty.		09 Sep 2020 02:56:27

US3472020

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:45:01

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:59:03
User entered '0'		09 Sep 2020 02:56:27

US3472020

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:45:01

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:59:03
User entered 'UN UNK 2016'		09 Sep 2020 02:56:27

US3472020

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:45:01

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:59:03
User entered '0'		09 Sep 2020 02:56:27

US3472020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:00:02
User entered 'Yes (Y)'		09 Sep 2020 03:00:08

US3472020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:00:02
User entered 'No (N)'		09 Sep 2020 03:00:08

US3472020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:00:02
User entered 'No (N)'		09 Sep 2020 03:00:08

US3472020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:00:02
User entered 'No (N)'		09 Sep 2020 03:00:08

US3472020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:45:01

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:00:02
User entered 'No (N)'		09 Sep 2020 03:00:08

US3472020

Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:00:02
User entered 'No (N)'		09 Sep 2020 03:00:08

US3472020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:00:02
User entered 'No (N)'		09 Sep 2020 03:00:08

US3472020

Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:00:02
User entered 'No (N)'		09 Sep 2020 03:00:08

US3472020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:00:02
User entered 'No (N)'		09 Sep 2020 03:00:08

US3472020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:00:02
User entered 'No (N)'		09 Sep 2020 03:00:08

US3472020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:00:02
User entered 'No (N)'		09 Sep 2020 03:00:08

US3472020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:45:01

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:00:02
User entered 'Yes (Y)'		09 Sep 2020 03:00:08

US3472020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:45:01

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:00:02
User entered 'Works with a home health agency. Does not interact with patients.'		09 Sep 2020 03:00:08

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:45:01

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 03:00:08

US3472020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:00:02
User entered '0'		09 Sep 2020 03:00:08

US3472020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:00:02
User entered '0'		09 Sep 2020 03:00:08

US3472020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:00:02
User entered '0'		09 Sep 2020 03:00:08

US3472020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:00:02
User entered '0'		09 Sep 2020 03:00:08

US3472020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:00:02
User entered '1'		09 Sep 2020 03:00:08

US3472020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:45:01

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 03:00:08

US3472020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:45:01

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:48:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:00:02
User entered empty.		09 Sep 2020 03:00:08

US3472020

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:45:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:00:12
User entered 'Yes (Y)'		09 Sep 2020 03:02:15

US3472020

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:45:01

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:00:12
User entered '8 Sep 2020'		09 Sep 2020 03:02:15

US3472020

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:00:12
User entered 'Clinic (Clinic)'		09 Sep 2020 03:02:15

US3472020

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:45:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User entered 'VISIT1'	System	09 Sep 2020 03:02:15

US3472020

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:00:20
User entered '08 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 16:40:13

US3472020

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:00:20
User entered '112014'	RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 16:40:13

US3472020

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:00:20
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 16:40:13

US3472020

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:45:01

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)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:00:20
User entered 'No (N)'		09 Sep 2020 03:05:04

US3472020

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:45:01

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)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:00:20
User entered 'No (N)'		09 Sep 2020 03:05:04

US3472020

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:00:20
User entered 'No (N)'		09 Sep 2020 03:05:04

US3472020

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:45:01

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:00:20
User entered 'No (N)'		09 Sep 2020 03:05:04

US3472020

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:45:01

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:00:20
User entered 'No (N)'		09 Sep 2020 03:05:04

US3472020

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:45:01

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:12:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
User closed query 'Per CDM: This field requires a Yes or No response. Please complete. (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Dec 2020 08:32:28
Query 'Per CDM: This field requires a Yes or No response. Please complete. answered with 'Updated.' (Site from DM).	Jie Ho (b) (4)	07 Dec 2020 21:17:16
User entered 'No (N)'	Jie Ho (b) (4)	07 Dec 2020 21:17:11
User opened query 'Per CDM: This field requires a Yes or No response. Please complete. (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 21:52:05
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:38:01
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:38:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:45:01

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:03:31
User entered missing code ND - Not Done.		09 Sep 2020 03:17:52

US3472020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:45:01

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:03:31
User entered missing code ND - Not Done.		09 Sep 2020 03:17:52

US3472020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:45:01

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:03:31
User entered missing code ND - Not Done.		09 Sep 2020 03:17:52

US3472020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:45:01

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:03:31
User entered missing code ND - Not Done.		09 Sep 2020 03:17:52

US3472020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User accepted default value 'Pre-Dose (PREDOSE)'		09 Sep 2020 03:17:52

US3472020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:03:31
User entered 'Yes (Y)'		09 Sep 2020 03:17:52

US3472020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:03:31
User entered '8 Sep 2020'		09 Sep 2020 03:17:52

US3472020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:03:31
User entered '11:16'		09 Sep 2020 03:17:52

US3472020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User entered '8 Sep 2020 11:16'	System	09 Sep 2020 03:17:52

US3472020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:03:31
User entered '36.2' C		09 Sep 2020 03:17:52

US3472020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:03:31
User entered 'Oral (Oral)'		09 Sep 2020 03:17:52

US3472020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:03:31
User entered empty.		09 Sep 2020 03:17:52

US3472020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:03:31
User entered '67'		09 Sep 2020 03:17:52

US3472020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User entered 'bpm'	System	09 Sep 2020 03:17:52

US3472020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:03:31
User entered '16'		09 Sep 2020 03:17:52

US3472020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User entered 'breaths/min'	System	09 Sep 2020 03:17:52

US3472020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:03:31
User entered '108'		09 Sep 2020 03:17:52

US3472020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User entered 'mmHg'	System	09 Sep 2020 03:17:52

US3472020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:03:31
User entered '66'		09 Sep 2020 03:17:52

US3472020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User entered 'mmHg'	System	09 Sep 2020 03:17:52

US3472020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:45:01

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:03:31
User entered missing code ND - Not Done.		09 Sep 2020 03:17:52

US3472020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:45:01

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:03:31
User entered missing code ND - Not Done.		09 Sep 2020 03:17:52

US3472020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User accepted default value 'Post-Dose (POSTDOSE)'		09 Sep 2020 03:17:52

US3472020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:03:31
User entered 'Yes (Y)'		09 Sep 2020 03:17:52

US3472020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:03:31
User entered '8 Sep 2020'		09 Sep 2020 03:17:52

US3472020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:03:31
User entered '14:42'		09 Sep 2020 03:17:52

US3472020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User entered '8 Sep 2020 14:42'	System	09 Sep 2020 03:17:52

US3472020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:03:31
User entered '36.8' C		09 Sep 2020 03:17:52

US3472020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:03:31
User entered 'Oral (Oral)'		09 Sep 2020 03:17:52

US3472020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:03:31
User entered empty.		09 Sep 2020 03:17:52

US3472020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:03:31
User entered '74'		09 Sep 2020 03:17:52

US3472020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User entered 'bpm'	System	09 Sep 2020 03:17:52

US3472020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:03:31
User entered '16'		09 Sep 2020 03:17:52

US3472020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User entered 'breaths/min'	System	09 Sep 2020 03:17:52

US3472020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:03:31
User entered '100'		09 Sep 2020 03:17:52

US3472020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User entered 'mmHg'	System	09 Sep 2020 03:17:52

US3472020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:03:31
User entered '60'		09 Sep 2020 03:17:52

US3472020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User entered 'mmHg'	System	09 Sep 2020 03:17:52

US3472020

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:45:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:03:40
User entered 'No (N)'		09 Sep 2020 03:18:10

US3472020

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:45:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:03:40
User entered empty.		09 Sep 2020 03:18:10

US3472020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:45:01

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:03:47
User entered 'Yes (Y)'	Juan Diego Ramirez (b) (4)	08 Sep 2020 18:18:25

US3472020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:45:01

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:03:47
User entered empty.	Juan Diego Ramirez (b) (4)	08 Sep 2020 18:18:25

US3472020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:45:01

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)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:03:47
User entered empty.	Juan Diego Ramirez (b) (4)	08 Sep 2020 18:18:25

US3472020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:45:01

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User entered 'MRNA-1273 OR PLACEBO'	System	08 Sep 2020 18:18:25

US3472020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:45:01

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:03:47
User entered '08 Sep 2020'	Juan Diego Ramirez (b) (4)	08 Sep 2020 18:18:25

US3472020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:03:47
User entered '14:10'	Juan Diego Ramirez (b) (4)	08 Sep 2020 18:18:25

US3472020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User entered '08 Sep 2020 14:10'	System	08 Sep 2020 18:18:25

US3472020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:03:47
User entered 'Right Arm (RIGHT ARM)'	Juan Diego Ramirez (b) (4)	08 Sep 2020 18:18:25

US3472020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:03:47
User entered 'ONCE'	System	08 Sep 2020 18:18:25

US3472020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:45:01

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User entered 'INTRAMUSCULAR'	System	08 Sep 2020 18:18:25

US3472020

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:45:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:04:06
User entered 'Yes (Y)'		09 Sep 2020 03:21:00

US3472020

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:45:01

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:04:06
User entered '8 Sep 2020'		09 Sep 2020 03:21:00

US3472020

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:45:01

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:04:06
User entered '13:17'		09 Sep 2020 03:21:00

US3472020

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User entered '8 Sep 2020 13:17'	System	09 Sep 2020 03:21:00

US3472020

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:45:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:04:14
User entered '8 Sep 2020'		09 Sep 2020 03:22:22

US3472020

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:45:01

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	09 Sep 2020 03:22:22

US3472020

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:45:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:04:14
User entered 'Yes (Y)'		09 Sep 2020 03:22:22

US3472020

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:45:01

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:04:14
User entered '12:50'		09 Sep 2020 03:22:22

US3472020

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User entered '8 Sep 2020 12:50'	System	09 Sep 2020 03:22:22

US3472020

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:45:01

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	09 Sep 2020 03:22:22

US3472020

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:45:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:04:14
User entered 'No (N)'		09 Sep 2020 03:22:22

US3472020

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:45:01

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:04:14
User entered empty.		09 Sep 2020 03:22:22

US3472020

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User entered empty.	System	09 Sep 2020 03:22:22

US3472020

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:04:32
User entered 'Yes (Y)'		09 Sep 2020 03:22:38

US3472020

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:45:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User entered '1'	System	09 Sep 2020 03:22:38

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
Data entry locked.	System	08 Sep 2020 18:18:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:45:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-08T14:44:10', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '52f61333-20ca-4fea-8abf-48454164de0a'	System	08 Sep 2020 18:44:46
User entered 'Yes (Y)'	System	08 Sep 2020 18:44:46

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:45:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-08T14:44:17', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '52f61333-20ca-4fea-8abf-48454164de0a'	System	08 Sep 2020 18:44:46
User entered '98.2'	System	08 Sep 2020 18:44:46

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-08T14:44:27', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '52f61333-20ca-4fea-8abf-48454164de0a'	System	08 Sep 2020 18:44:46
User entered 'No (N)'	System	08 Sep 2020 18:44:46

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:45:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-08T14:44:42', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '52f61333-20ca-4fea-8abf-48454164de0a'	System	08 Sep 2020 18:44:46
User entered '08 Sep 2020 14:44'	System	08 Sep 2020 18:44:46

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:45:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '08 Sep 2020 14:30'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:45:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '08 Sep 2020 17:00'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
Data entry locked.	System	08 Sep 2020 18:18:25
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '08 Sep 2020 17:55'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
Data entry locked.	System	08 Sep 2020 18:18:25
User entered 'Day 2'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:45:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-09T19:20:48', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'ce63ccde-af90-496f-95e4-92529dc43cbd'	System	09 Sep 2020 23:21:07
User entered 'Yes (Y)'	System	09 Sep 2020 23:21:07

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:45:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-09T19:20:53', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'ce63ccde-af90-496f-95e4-92529dc43cbd' User entered '98.0'	System	09 Sep 2020 23:21:07
	System	09 Sep 2020 23:21:07

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-09T19:20:57', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'ce63ccde-af90-496f-95e4-92529dc43cbd'	System	09 Sep 2020 23:21:07
User entered 'No (N)'	System	09 Sep 2020 23:21:07

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:45:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-09T19:21:05', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'ce63ccde-af90-496f-95e4-92529dc43cbd'	System	09 Sep 2020 23:21:07
User entered '09 Sep 2020 19:21'	System	09 Sep 2020 23:21:07

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:45:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:45:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
Data entry locked.	System	08 Sep 2020 18:18:25
User entered 'Day 3'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:45:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-10T18:58:07', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '17415514-3f79-4474-9586-f77218f6fab0'	System	10 Sep 2020 22:59:03
User entered 'Yes (Y)'	System	10 Sep 2020 22:59:03

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:45:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-10T18:58:49', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '17415514-3f79-4474-9586-f77218f6fab0'	System	10 Sep 2020 22:59:03
User entered '97.4'	System	10 Sep 2020 22:59:03

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-10T18:58:52', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '17415514-3f79-4474-9586-f77218f6fab0'	System	10 Sep 2020 22:59:03
User entered 'No (N)'	System	10 Sep 2020 22:59:03

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:45:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-10T18:58:58', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '17415514-3f79-4474-9586-f77218f6fab0'	System	10 Sep 2020 22:59:03
User entered '10 Sep 2020 18:58'	System	10 Sep 2020 22:59:03

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:45:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:45:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
Data entry locked.	System	08 Sep 2020 18:18:25
User entered 'Day 4'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:45:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-11T21:48:30', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'cd40d721-b007-4157-903c-a792b7f5ccbf'	System	12 Sep 2020 01:48:48
User entered 'Yes (Y)'	System	12 Sep 2020 01:48:48

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:45:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-11T21:48:36', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'cd40d721-b007-4157-903c-a792b7f5ccbf'	System	12 Sep 2020 01:48:48
User entered '97.1'	System	12 Sep 2020 01:48:48

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-11T21:48:41', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'cd40d721-b007-4157-903c-a792b7f5ccbf'	System	12 Sep 2020 01:48:48
User entered 'No (N)'	System	12 Sep 2020 01:48:48

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:45:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-11T21:48:45', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'cd40d721-b007-4157-903c-a792b7f5ccb'	System	12 Sep 2020 01:48:48
User entered '11 Sep 2020 21:48'	System	12 Sep 2020 01:48:48

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:45:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:45:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
Data entry locked.	System	08 Sep 2020 18:18:25
User entered 'Day 5'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:45:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-12T20:23:22', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'f040d79a-db3a-45cb-85cf-ef1a610d5b02'	System	13 Sep 2020 00:24:18
User entered 'Yes (Y)'	System	13 Sep 2020 00:24:18

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:45:01

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-12T20:23:27', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'f040d79a-db3a-45cb-85cf-ef1a610d5b02'	System	13 Sep 2020 00:24:18
User entered '98.6'	System	13 Sep 2020 00:24:18

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-12T20:23:30', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'f040d79a-db3a-45cb-85cf-ef1a610d5b02'	System	13 Sep 2020 00:24:18
User entered 'No (N)'	System	13 Sep 2020 00:24:18

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:45:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-12T20:23:35', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'f040d79a-db3a-45cb-85cf-ef1a610d5b02'	System	13 Sep 2020 00:24:18
User entered '12 Sep 2020 20:23'	System	13 Sep 2020 00:24:18

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:45:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:45:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
Data entry locked.	System	08 Sep 2020 18:18:25
User entered 'Day 6'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:45:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-13T21:34:20', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '688a5239-bf8b-415e-b47c-383dcde76e73'	System	14 Sep 2020 01:34:41
User entered 'Yes (Y)'	System	14 Sep 2020 01:34:41

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:45:01

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-13T21:34:25', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '688a5239-bf8b-415e-b47c-383dcde76e73'	System	14 Sep 2020 01:34:41
User entered '96.6'	System	14 Sep 2020 01:34:41

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-13T21:34:28', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '688a5239-bf8b-415e-b47c-383dcde76e73'	System	14 Sep 2020 01:34:41
User entered 'No (N)'	System	14 Sep 2020 01:34:41

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:45:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-13T21:34:38', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '688a5239-bf8b-415e-b47c-383dcde76e73'	System	14 Sep 2020 01:34:41
User entered '13 Sep 2020 21:34'	System	14 Sep 2020 01:34:41

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:45:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:45:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
Data entry locked.	System	08 Sep 2020 18:18:25
User entered 'Day 7'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:45:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-14T20:35:55', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '7db14e3e-d18a-4a83-bb1f-b6bd758878dc'	System	15 Sep 2020 00:36:18
User entered 'Yes (Y)'	System	15 Sep 2020 00:36:18

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:45:01

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-14T20:36:07', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '7db14e3e-d18a-4a83-bb1f-b6bd758878dc'	System	15 Sep 2020 00:36:18
User entered '97.6'	System	15 Sep 2020 00:36:18

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-14T20:36:10', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '7db14e3e-d18a-4a83-bb1f-b6bd758878dc'	System	15 Sep 2020 00:36:18
User entered 'No (N)'	System	15 Sep 2020 00:36:18

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:45:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-14T20:36:15', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '7db14e3e-d18a-4a83-bb1f-b6bd758878dc'	System	15 Sep 2020 00:36:18
User entered '14 Sep 2020 20:36'	System	15 Sep 2020 00:36:18

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:45:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:45:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
Data entry locked.	System	08 Sep 2020 18:18:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:45:01

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 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-08T14:45:37', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '39057ec9-f2a5-404d-b5d1-730774fd7e5d'	System	08 Sep 2020 18:46:55
User entered 'None (1)'	System	08 Sep 2020 18:46:55

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-08T14:46:27', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '39057ec9-f2a5-404d-b5d1-730774fd7e5d'	System	08 Sep 2020 18:46:55
User entered 'No (N)'	System	08 Sep 2020 18:46:55

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-08T14:46:34', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '39057ec9-f2a5-404d-b5d1-730774fd7e5d'	System	08 Sep 2020 18:46:55
User entered 'No (N)'	System	08 Sep 2020 18:46:55

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:45:01

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 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-08T14:46:45', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '39057ec9-f2a5-404d-b5d1-730774fd7e5d'	System	08 Sep 2020 18:46:55
User entered 'None (1)'	System	08 Sep 2020 18:46:55

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:45:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-08T14:46:52', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '39057ec9-f2a5-404d-b5d1-730774fd7e5d' User entered '08 Sep 2020 14:46'	System	08 Sep 2020 18:46:55
	System	08 Sep 2020 18:46:55

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:45:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '08 Sep 2020 14:30'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:45:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '08 Sep 2020 17:00'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
Data entry locked.	System	08 Sep 2020 18:18:25
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

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 01:18:36

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

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 01:18:36

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

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 01:18:36

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '08 Sep 2020 17:55'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
Data entry locked.	System	08 Sep 2020 18:18:25
User entered 'Day 2'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:45:01

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 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-09T19:21:31', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '05f2e7c5-55d2-4386-bef1-c1ab4a5385e6'	System	09 Sep 2020 23:22:18
User entered 'None (1)'	System	09 Sep 2020 23:22:18

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-09T19:21:34', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '05f2e7c5-55d2-4386-bef1-c1ab4a5385e6'	System	09 Sep 2020 23:22:18
User entered 'No (N)'	System	09 Sep 2020 23:22:18

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-09T19:21:37', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '05f2e7c5-55d2-4386-bef1-c1ab4a5385e6'	System	09 Sep 2020 23:22:18
User entered 'No (N)'	System	09 Sep 2020 23:22:18

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:45:01

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 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-09T19:22:06', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '05f2e7c5-55d2-4386-bef1-c1ab4a5385e6'	System	09 Sep 2020 23:22:18
User entered 'None (1)'	System	09 Sep 2020 23:22:18

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:45:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-09T19:22:15', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '05f2e7c5-55d2-4386-bef1-c1ab4a5385e6'	System	09 Sep 2020 23:22:18
User entered '09 Sep 2020 19:22'	System	09 Sep 2020 23:22:18

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:45:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:45:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
Data entry locked.	System	08 Sep 2020 18:18:25
User entered 'Day 3'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:45:01

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 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-10T18:59:13', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '3ca68a8b-8f02-4ce2-a07b-0dac310b70cf'	System	10 Sep 2020 22:59:50
User entered 'None (1)'	System	10 Sep 2020 22:59:50

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-10T18:59:16', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '3ca68a8b-8f02-4ce2-a07b-0dac310b70cf'	System	10 Sep 2020 22:59:50
User entered 'No (N)'	System	10 Sep 2020 22:59:50

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-10T18:59:20', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '3ca68a8b-8f02-4ce2-a07b-0dac310b70cf'	System	10 Sep 2020 22:59:50
User entered 'No (N)'	System	10 Sep 2020 22:59:50

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:45:01

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 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-10T18:59:39', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '3ca68a8b-8f02-4ce2-a07b-0dac310b70cf'	System	10 Sep 2020 22:59:50
User entered 'None (1)'	System	10 Sep 2020 22:59:50

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:45:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-10T18:59:45', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '3ca68a8b-8f02-4ce2-a07b-0dac310b70cf' User entered '10 Sep 2020 18:59'	System	10 Sep 2020 22:59:50
	System	10 Sep 2020 22:59:50

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:45:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:45:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
Data entry locked.	System	08 Sep 2020 18:18:25
User entered 'Day 4'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:45:01

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 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-11T21:48:49', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '41123d88-bae5-4cda-836d-18dd43594c9a'	System	12 Sep 2020 01:49:16
User entered 'None (1)'	System	12 Sep 2020 01:49:16

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-11T21:48:52', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '41123d88-bae5-4cda-836d-18dd43594c9a'	System	12 Sep 2020 01:49:16
User entered 'No (N)'	System	12 Sep 2020 01:49:16

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-11T21:48:55', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '41123d88-bae5-4cda-836d-18dd43594c9a'	System	12 Sep 2020 01:49:16
User entered 'No (N)'	System	12 Sep 2020 01:49:16

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:45:01

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 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-11T21:49:07', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '41123d88-bae5-4cda-836d-18dd43594c9a'	System	12 Sep 2020 01:49:16
User entered 'None (1)'	System	12 Sep 2020 01:49:16

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:45:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-11T21:49:12', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '41123d88-bae5-4cda-836d-18dd43594c9a'	System	12 Sep 2020 01:49:16
User entered '11 Sep 2020 21:49'	System	12 Sep 2020 01:49:16

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:45:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:45:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
Data entry locked.	System	08 Sep 2020 18:18:25
User entered 'Day 5'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:45:01

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 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-12T20:23:39', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '69431b03-4b9e-4374-86e9-401c5c33e28f'	System	13 Sep 2020 00:24:38
User entered 'None (1)'	System	13 Sep 2020 00:24:38

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-12T20:23:42', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '69431b03-4b9e-4374-86e9-401c5c33e28f'	System	13 Sep 2020 00:24:38
User entered 'No (N)'	System	13 Sep 2020 00:24:38

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-12T20:23:45', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '69431b03-4b9e-4374-86e9-401c5c33e28f'	System	13 Sep 2020 00:24:38
User entered 'No (N)'	System	13 Sep 2020 00:24:38

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:45:01

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 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-12T20:23:56', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '69431b03-4b9e-4374-86e9-401c5c33e28f'	System	13 Sep 2020 00:24:38
User entered 'None (1)'	System	13 Sep 2020 00:24:38

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:45:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-12T20:24:06', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '69431b03-4b9e-4374-86e9-401c5c33e28f'	System	13 Sep 2020 00:24:38
User entered '12 Sep 2020 20:24'	System	13 Sep 2020 00:24:38

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:45:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:45:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
Data entry locked.	System	08 Sep 2020 18:18:25
User entered 'Day 6'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:45:01

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 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-13T21:34:42', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '6f554ba5-c6a5-43b3-8624-bd5b1d35c3bd'	System	14 Sep 2020 01:35:09
User entered 'None (1)'	System	14 Sep 2020 01:35:09

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-13T21:34:45', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '6f554ba5-c6a5-43b3-8624-bd5b1d35c3bd'	System	14 Sep 2020 01:35:09
User entered 'No (N)'	System	14 Sep 2020 01:35:09

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-13T21:34:48', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '6f554ba5-c6a5-43b3-8624-bd5b1d35c3bd'	System	14 Sep 2020 01:35:09
User entered 'No (N)'	System	14 Sep 2020 01:35:09

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:45:01

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 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-13T21:34:57', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '6f554ba5-c6a5-43b3-8624-bd5b1d35c3bd'	System	14 Sep 2020 01:35:09
User entered 'None (1)'	System	14 Sep 2020 01:35:09

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:45:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-13T21:35:04', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '6f554ba5-c6a5-43b3-8624-bd5b1d35c3bd'	System	14 Sep 2020 01:35:09
User entered '13 Sep 2020 21:35'	System	14 Sep 2020 01:35:09

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:45:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:45:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
Data entry locked.	System	08 Sep 2020 18:18:25
User entered 'Day 7'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:45:01

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 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-14T20:36:47', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '96a3c6a5-8e56-4176-9c8d-ea06fb124017'	System	15 Sep 2020 00:37:16
User entered 'None (1)'	System	15 Sep 2020 00:37:16

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-14T20:36:51', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '96a3c6a5-8e56-4176-9c8d-ea06fb124017'	System	15 Sep 2020 00:37:16
User entered 'No (N)'	System	15 Sep 2020 00:37:16

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-14T20:36:54', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '96a3c6a5-8e56-4176-9c8d-ea06fb124017'	System	15 Sep 2020 00:37:16
User entered 'No (N)'	System	15 Sep 2020 00:37:16

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:45:01

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 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-14T20:37:06', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '96a3c6a5-8e56-4176-9c8d-ea06fb124017'	System	15 Sep 2020 00:37:16
User entered 'None (1)'	System	15 Sep 2020 00:37:16

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:45:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-14T20:37:13', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '96a3c6a5-8e56-4176-9c8d-ea06fb124017'	System	15 Sep 2020 00:37:16
User entered '14 Sep 2020 20:37'	System	15 Sep 2020 00:37:16

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:45:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:45:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
Data entry locked.	System	08 Sep 2020 18:18:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:45:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-08T14:46:59', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '91102d68-8286-4610-9fbe-385eec6faec'	System	08 Sep 2020 18:47:32
User entered 'None (0)'	System	08 Sep 2020 18:47:32

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:45:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-08T14:47:04', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '91102d68-8286-4610-9fbe-385eec6faec'	System	08 Sep 2020 18:47:32
User entered 'None (0)'	System	08 Sep 2020 18:47:32

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:45:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-08T14:47:08', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '91102d68-8286-4610-9fbe-385eec6faec'	System	08 Sep 2020 18:47:32
User entered 'None (0)'	System	08 Sep 2020 18:47:32

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:45:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-08T14:47:12', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '91102d68-8286-4610-9fbe-385eec6faec'	System	08 Sep 2020 18:47:32
User entered 'None (0)'	System	08 Sep 2020 18:47:32

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:45:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-08T14:47:15', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '91102d68-8286-4610-9fbe-385eec6faec'	System	08 Sep 2020 18:47:32
User entered 'None (0)'	System	08 Sep 2020 18:47:32

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:45:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-08T14:47:18', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '91102d68-8286-4610-9fbe-385eec6faec'	System	08 Sep 2020 18:47:32
User entered 'None (0)'	System	08 Sep 2020 18:47:32

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:45:01

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 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-08T14:47:23', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '91102d68-8286-4610-9fbe-385eec6faec'	System	08 Sep 2020 18:47:32
User entered 'No (N)'	System	08 Sep 2020 18:47:32

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:45:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-08T14:47:29', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '91102d68-8286-4610-9fbe-385eec6faec'	System	08 Sep 2020 18:47:32
User entered '08 Sep 2020 14:47'	System	08 Sep 2020 18:47:32

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:45:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '08 Sep 2020 14:30'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:45:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '08 Sep 2020 17:00'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
Data entry locked.	System	08 Sep 2020 18:18:25
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-09T09:31:37', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '12ed23f5-ce53-47c8-80e8-9a520cd5b36a'	System	09 Sep 2020 13:32:56
User entered 'No interference with activity (1)'	System	09 Sep 2020 13:32:56

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-09T09:31:52', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '12ed23f5-ce53-47c8-80e8-9a520cd5b36a'	System	09 Sep 2020 13:32:56
User entered 'No interference with activity (1)'	System	09 Sep 2020 13:32:56

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-09T09:32:00', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '12ed23f5-ce53-47c8-80e8-9a520cd5b36a'	System	09 Sep 2020 13:32:56
User entered 'None (0)'	System	09 Sep 2020 13:32:56

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-09T09:32:13', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '12ed23f5-ce53-47c8-80e8-9a520cd5b36a'	System	09 Sep 2020 13:32:56
User entered 'None (0)'	System	09 Sep 2020 13:32:56

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-09T09:32:29', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '12ed23f5-ce53-47c8-80e8-9a520cd5b36a'	System	09 Sep 2020 13:32:56
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	09 Sep 2020 13:32:56

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-09T09:32:32', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '12ed23f5-ce53-47c8-80e8-9a520cd5b36a'	System	09 Sep 2020 13:32:56
User entered 'None (0)'	System	09 Sep 2020 13:32:56

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

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 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-09T09:32:38', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '12ed23f5-ce53-47c8-80e8-9a520cd5b36a'	System	09 Sep 2020 13:32:56
User entered 'No (N)'	System	09 Sep 2020 13:32:56

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-09T09:32:52', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '12ed23f5-ce53-47c8-80e8-9a520cd5b36a'	System	09 Sep 2020 13:32:56
User entered '09 Sep 2020 09:32'	System	09 Sep 2020 13:32:56

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '08 Sep 2020 17:55'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
Data entry locked.	System	08 Sep 2020 18:18:25
User entered 'Day 2'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:45:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-09T19:22:24', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'c6a237a0-4a3f-4f0d-b860-14d4e3531fe0'	System	09 Sep 2020 23:23:09
User entered 'No interference with activity (1)'	System	09 Sep 2020 23:23:09

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:45:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-09T19:22:27', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'c6a237a0-4a3f-4f0d-b860-14d4e3531fe0'	System	09 Sep 2020 23:23:09
User entered 'No interference with activity (1)'	System	09 Sep 2020 23:23:09

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:45:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-09T19:22:32', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'c6a237a0-4a3f-4f0d-b860-14d4e3531fe0'	System	09 Sep 2020 23:23:09
User entered 'None (0)'	System	09 Sep 2020 23:23:09

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:45:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-09T19:22:34', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'c6a237a0-4a3f-4f0d-b860-14d4e3531fe0'	System	09 Sep 2020 23:23:09
User entered 'None (0)'	System	09 Sep 2020 23:23:09

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:45:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-09T19:22:40', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'c6a237a0-4a3f-4f0d-b860-14d4e3531fe0'	System	09 Sep 2020 23:23:09
User entered 'None (0)'	System	09 Sep 2020 23:23:09

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:45:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-09T19:22:48', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'c6a237a0-4a3f-4f0d-b860-14d4e3531fe0'	System	09 Sep 2020 23:23:09
User entered 'No interference with activity (1)'	System	09 Sep 2020 23:23:09

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:45:01

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 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-09T19:22:53', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'c6a237a0-4a3f-4f0d-b860-14d4e3531fe0'	System	09 Sep 2020 23:23:09
User entered 'No (N)'	System	09 Sep 2020 23:23:09

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:45:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-09T19:23:05', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'c6a237a0-4a3f-4f0d-b860-14d4e3531fe0'	System	09 Sep 2020 23:23:09
User entered '09 Sep 2020 19:23'	System	09 Sep 2020 23:23:09

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:45:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:45:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
Data entry locked.	System	08 Sep 2020 18:18:25
User entered 'Day 3'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:45:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-10T18:59:51', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '914c0570-515b-43b8-bfe4-c3ec23bf74e9'	System	10 Sep 2020 23:00:29
User entered 'No interference with activity (1)'	System	10 Sep 2020 23:00:29

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:45:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-10T18:59:55', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '914c0570-515b-43b8-bfe4-c3ec23bf74e9'	System	10 Sep 2020 23:00:29
User entered 'No interference with activity (1)'	System	10 Sep 2020 23:00:29

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:45:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-10T18:59:59', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '914c0570-515b-43b8-bfe4-c3ec23bf74e9'	System	10 Sep 2020 23:00:29
User entered 'None (0)'	System	10 Sep 2020 23:00:29

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:45:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-10T19:00:07', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '914c0570-515b-43b8-bfe4-c3ec23bf74e9'	System	10 Sep 2020 23:00:29
User entered 'None (0)'	System	10 Sep 2020 23:00:29

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:45:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-10T19:00:11', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '914c0570-515b-43b8-bfe4-c3ec23bf74e9'	System	10 Sep 2020 23:00:29
User entered 'None (0)'	System	10 Sep 2020 23:00:29

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:45:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-10T19:00:14', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '914c0570-515b-43b8-bfe4-c3ec23bf74e9'	System	10 Sep 2020 23:00:29
User entered 'No interference with activity (1)'	System	10 Sep 2020 23:00:29

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:45:01

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 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-10T19:00:18', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '914c0570-515b-43b8-bfe4-c3ec23bf74e9'	System	10 Sep 2020 23:00:29
User entered 'No (N)'	System	10 Sep 2020 23:00:29

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:45:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-10T19:00:27', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '914c0570-515b-43b8-bfe4-c3ec23bf74e9'	System	10 Sep 2020 23:00:29
User entered '10 Sep 2020 19:00'	System	10 Sep 2020 23:00:29

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:45:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:45:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
Data entry locked.	System	08 Sep 2020 18:18:25
User entered 'Day 4'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:45:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-11T21:49:20', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '23e9550b-3e1f-47f9-ad05-1b3a75e4a563'	System	12 Sep 2020 01:49:57
User entered 'None (0)'	System	12 Sep 2020 01:49:57

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:45:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-11T21:49:28', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '23e9550b-3e1f-47f9-ad05-1b3a75e4a563'	System	12 Sep 2020 01:49:57
User entered 'None (0)'	System	12 Sep 2020 01:49:57

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:45:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-11T21:49:34', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '23e9550b-3e1f-47f9-ad05-1b3a75e4a563'	System	12 Sep 2020 01:49:57
User entered 'None (0)'	System	12 Sep 2020 01:49:57

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:45:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-11T21:49:36', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '23e9550b-3e1f-47f9-ad05-1b3a75e4a563'	System	12 Sep 2020 01:49:57
User entered 'None (0)'	System	12 Sep 2020 01:49:57

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:45:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-11T21:49:39', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '23e9550b-3e1f-47f9-ad05-1b3a75e4a563'	System	12 Sep 2020 01:49:57
User entered 'None (0)'	System	12 Sep 2020 01:49:57

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:45:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-11T21:49:41', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '23e9550b-3e1f-47f9-ad05-1b3a75e4a563'	System	12 Sep 2020 01:49:57
User entered 'No interference with activity (1)'	System	12 Sep 2020 01:49:57

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:45:01

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 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-11T21:49:46', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '23e9550b-3e1f-47f9-ad05-1b3a75e4a563'	System	12 Sep 2020 01:49:57
User entered 'No (N)'	System	12 Sep 2020 01:49:57

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:45:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-11T21:49:54', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '23e9550b-3e1f-47f9-ad05-1b3a75e4a563'	System	12 Sep 2020 01:49:57
User entered '11 Sep 2020 21:49'	System	12 Sep 2020 01:49:57

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:45:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:45:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
Data entry locked.	System	08 Sep 2020 18:18:25
User entered 'Day 5'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:45:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-12T20:24:17', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '4191aa2e-8cb6-4650-a59b-903d1f8dad38'	System	13 Sep 2020 00:25:09
User entered 'No interference with activity (1)'	System	13 Sep 2020 00:25:09

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:45:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-12T20:24:19', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '4191aa2e-8cb6-4650-a59b-903d1f8dad38'	System	13 Sep 2020 00:25:09
User entered 'No interference with activity (1)'	System	13 Sep 2020 00:25:09

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:45:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-12T20:24:22', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '4191aa2e-8cb6-4650-a59b-903d1f8dad38'	System	13 Sep 2020 00:25:09
User entered 'None (0)'	System	13 Sep 2020 00:25:09

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:45:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-12T20:24:25', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '4191aa2e-8cb6-4650-a59b-903d1f8dad38'	System	13 Sep 2020 00:25:09
User entered 'None (0)'	System	13 Sep 2020 00:25:09

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:45:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-12T20:24:27', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '4191aa2e-8cb6-4650-a59b-903d1f8dad38'	System	13 Sep 2020 00:25:09
User entered 'None (0)'	System	13 Sep 2020 00:25:09

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:45:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-12T20:24:30', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '4191aa2e-8cb6-4650-a59b-903d1f8dad38'	System	13 Sep 2020 00:25:09
User entered 'No interference with activity (1)'	System	13 Sep 2020 00:25:09

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:45:01

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 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-12T20:24:35', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '4191aa2e-8cb6-4650-a59b-903d1f8dad38'	System	13 Sep 2020 00:25:09
User entered 'No (N)'	System	13 Sep 2020 00:25:09

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:45:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-12T20:24:46', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '4191aa2e-8cb6-4650-a59b-903d1f8dad38'	System	13 Sep 2020 00:25:09
User entered '12 Sep 2020 20:24'	System	13 Sep 2020 00:25:09

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:45:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:45:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
Data entry locked.	System	08 Sep 2020 18:18:25
User entered 'Day 6'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:45:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-13T21:35:09', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '6796537a-ff27-405f-814d-400c03682643'	System	14 Sep 2020 01:35:49
User entered 'None (0)'	System	14 Sep 2020 01:35:49

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:45:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-13T21:35:14', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '6796537a-ff27-405f-814d-400c03682643'	System	14 Sep 2020 01:35:49
User entered 'None (0)'	System	14 Sep 2020 01:35:49

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:45:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-13T21:35:17', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '6796537a-ff27-405f-814d-400c03682643'	System	14 Sep 2020 01:35:49
User entered 'None (0)'	System	14 Sep 2020 01:35:49

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:45:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-13T21:35:30', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '6796537a-ff27-405f-814d-400c03682643'	System	14 Sep 2020 01:35:49
User entered 'None (0)'	System	14 Sep 2020 01:35:49

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:45:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-13T21:35:32', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '6796537a-ff27-405f-814d-400c03682643'	System	14 Sep 2020 01:35:49
User entered 'None (0)'	System	14 Sep 2020 01:35:49

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:45:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-13T21:35:34', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '6796537a-ff27-405f-814d-400c03682643'	System	14 Sep 2020 01:35:49
User entered 'None (0)'	System	14 Sep 2020 01:35:49

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:45:01

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 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-13T21:35:39', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '6796537a-ff27-405f-814d-400c03682643'	System	14 Sep 2020 01:35:49
User entered 'No (N)'	System	14 Sep 2020 01:35:49

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:45:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-13T21:35:45', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '6796537a-ff27-405f-814d-400c03682643'	System	14 Sep 2020 01:35:49
User entered '13 Sep 2020 21:35'	System	14 Sep 2020 01:35:49

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:45:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:45:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
Data entry locked.	System	08 Sep 2020 18:18:25
User entered 'Day 7'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:45:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-14T20:37:22', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '38ba4578-fd57-4ceb-84bc-677c58fdce2d'	System	15 Sep 2020 00:38:04
User entered 'No interference with activity (1)'	System	15 Sep 2020 00:38:04

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:45:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-14T20:37:29', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '38ba4578-fd57-4ceb-84bc-677c58fdce2d'	System	15 Sep 2020 00:38:04
User entered 'None (0)'	System	15 Sep 2020 00:38:04

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:45:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-14T20:37:31', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '38ba4578-fd57-4ceb-84bc-677c58fdce2d'	System	15 Sep 2020 00:38:04
User entered 'None (0)'	System	15 Sep 2020 00:38:04

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:45:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-14T20:37:35', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '38ba4578-fd57-4ceb-84bc-677c58fdce2d'	System	15 Sep 2020 00:38:04
User entered 'None (0)'	System	15 Sep 2020 00:38:04

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:45:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-14T20:37:38', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '38ba4578-fd57-4ceb-84bc-677c58fdce2d'	System	15 Sep 2020 00:38:04
User entered 'None (0)'	System	15 Sep 2020 00:38:04

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:45:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-14T20:37:44', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '38ba4578-fd57-4ceb-84bc-677c58fdce2d'	System	15 Sep 2020 00:38:04
User entered 'None (0)'	System	15 Sep 2020 00:38:04

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:45:01

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 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-14T20:37:48', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '38ba4578-fd57-4ceb-84bc-677c58fdce2d'	System	15 Sep 2020 00:38:04
User entered 'No (N)'	System	15 Sep 2020 00:38:04

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:45:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-14T20:37:57', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '38ba4578-fd57-4ceb-84bc-677c58fdce2d'	System	15 Sep 2020 00:38:04
User entered '14 Sep 2020 20:37'	System	15 Sep 2020 00:38:04

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:45:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:45:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 18:18:25

US3472020

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
Data entry locked.	System	15 Sep 2020 00:38:04
User entered 'Day 8'	System	15 Sep 2020 00:38:04

US3472020

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:45:01

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-16T10:41:36', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '097cb4cb-b76b-41f0-982f-eff0f6ef8949'	System	16 Sep 2020 14:41:45
User entered 'No interference with activity (1)'	System	16 Sep 2020 14:41:45

US3472020

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:45:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-16T10:41:41', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '097cb4cb-b76b-41f0-982f-eff0f6ef8949'	System	16 Sep 2020 14:41:45
User entered '16 Sep 2020 10:41'	System	16 Sep 2020 14:41:45

US3472020

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:45:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '15 Sep 2020 12:00'	System	15 Sep 2020 00:38:04

US3472020

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:45:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 00:38:04

US3472020

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
Data entry locked.	System	15 Sep 2020 00:38:04
User entered 'Day 9'	System	15 Sep 2020 00:38:04

US3472020

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 11 Aug 2021 22:45:01

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-16T22:51:15', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'ec4947c6-93db-4358-920e-aafb34564548'	System	17 Sep 2020 02:51:25
User entered 'None (0)'	System	17 Sep 2020 02:51:25

US3472020

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 11 Aug 2021 22:45:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-16T22:51:24', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'ec4947c6-93db-4358-920e-aafb34564548'	System	17 Sep 2020 02:51:25
User entered '16 Sep 2020 22:51'	System	17 Sep 2020 02:51:25

US3472020

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 11 Aug 2021 22:45:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 00:38:04

US3472020

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 11 Aug 2021 22:45:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 00:38:04

US3472020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
Data entry locked.	System	15 Sep 2020 00:38:04
User entered 'Day 8'	System	15 Sep 2020 00:38:04

US3472020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:45:01

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 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-16T10:41:47', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'c0734fdc-a9c0-4d0a-9891-7d4dbeb5abae'	System	16 Sep 2020 14:41:52
User entered 'No (N)'	System	16 Sep 2020 14:41:52

US3472020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:45:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-16T10:41:50', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'c0734fdc-a9c0-4d0a-9891-7d4dbeb5abae'	System	16 Sep 2020 14:41:52
User entered '16 Sep 2020 10:41'	System	16 Sep 2020 14:41:52

US3472020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:45:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '15 Sep 2020 12:00'	System	15 Sep 2020 00:38:04

US3472020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:45:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 00:38:04

US3472020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
Data entry locked.	System	15 Sep 2020 00:38:04
User entered 'Day 9'	System	15 Sep 2020 00:38:04

US3472020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:45:01

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 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-16T22:51:32', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '1fb8ef9b-ee6b-4c9b-b994-02f161f907d1'	System	17 Sep 2020 02:51:37
User entered 'No (N)'	System	17 Sep 2020 02:51:37

US3472020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:45:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-09-16T22:51:35', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '1fb8ef9b-ee6b-4c9b-b994-02f161f907d1'	System	17 Sep 2020 02:51:37
User entered '16 Sep 2020 22:51'	System	17 Sep 2020 02:51:37

US3472020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:45:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 00:38:04

US3472020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:45:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 00:38:04

US3472020

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:06:11
User entered 'Yes (Y)'		15 Sep 2020 20:52:38

US3472020

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:06:11
User entered '15 Sep 2020'		15 Sep 2020 20:52:38

US3472020

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:06:11
User entered 'Contact Made (CONTACT MADE)'		15 Sep 2020 20:52:38

US3472020

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:06:11
User entered empty.		15 Sep 2020 20:52:38

US3472020

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:06:45
User entered 'Yes (Y)'		15 Sep 2020 20:52:48

US3472020

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User entered '1'	System	15 Sep 2020 20:52:48

US3472020

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:21:23
User entered 'Yes (Y)'		23 Sep 2020 12:36:44

US3472020

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:21:23
User entered '22 Sep 2020'		23 Sep 2020 12:36:44

US3472020

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:21:23
User entered 'Contact Made (CONTACT MADE)'		23 Sep 2020 12:36:44

US3472020

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:21:23
User entered empty.		23 Sep 2020 12:36:44

US3472020

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:21:28
User entered 'Yes (Y)'		23 Sep 2020 12:37:02

US3472020

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User entered '1'	System	23 Sep 2020 12:37:02

US3472020

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:21:41
User entered 'Yes (Y)'		30 Sep 2020 19:56:53

US3472020

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:21:41
User entered '30 Sep 2020'		30 Sep 2020 19:56:53

US3472020

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:21:41
User entered 'Contact Made (CONTACT MADE)'		30 Sep 2020 19:56:53

US3472020

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:21:41
User entered empty.		30 Sep 2020 19:56:53

US3472020

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:21:46
User entered 'Yes (Y)'		30 Sep 2020 19:57:01

US3472020

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User entered '1'	System	30 Sep 2020 19:57:01

US3472020

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:45:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:57:13
User entered 'Yes (Y)'	Christopher Chianese (b) (4)	07 Oct 2020 16:03:32

US3472020

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:57:13
User entered '7 Oct 2020'	Christopher Chianese (b) (4)	07 Oct 2020 16:03:32

US3472020

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:57:13
User entered 'Clinic (Clinic)'	Christopher Chianese (b) (4)	07 Oct 2020 16:03:32

US3472020

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:45:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User entered 'VISIT2'	System	07 Oct 2020 16:03:32

US3472020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User accepted default value 'Pre-Dose (PREDOSE)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:10:29

US3472020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:57:19
User entered 'Yes (Y)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:10:29

US3472020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:57:19
User entered '7 Oct 2020'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:10:29

US3472020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:57:19
User entered '11:24'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:10:29

US3472020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User entered '7 Oct 2020 11:24'	System	07 Oct 2020 18:10:29

US3472020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:57:19
User entered '36.3' C	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:10:29

US3472020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:57:19
User entered 'Oral (Oral)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:10:29

US3472020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:57:19
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:10:29

US3472020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:57:19
User entered '71'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:10:29

US3472020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User entered 'bpm'	System	07 Oct 2020 18:10:29

US3472020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:57:19
User entered '14'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:10:29

US3472020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User entered 'breaths/min'	System	07 Oct 2020 18:10:29

US3472020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:57:19
User entered '123'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:10:29

US3472020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User entered 'mmHg'	System	07 Oct 2020 18:10:29

US3472020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:57:19
User entered '73'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:10:29

US3472020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User entered 'mmHg'	System	07 Oct 2020 18:10:29

US3472020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User accepted default value 'Post-Dose (POSTDOSE)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:10:29

US3472020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:57:19
User entered 'Yes (Y)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:10:29

US3472020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:57:19
User entered '7 Oct 2020'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:10:29

US3472020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:57:19
User entered '12:34'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:10:29

US3472020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User entered '7 Oct 2020 12:34'	System	07 Oct 2020 18:10:29

US3472020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:57:19
User entered '36.4' C	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:10:29

US3472020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:57:19
User entered 'Oral (Oral)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:10:29

US3472020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:57:19
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:10:29

US3472020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:57:19
User entered '63'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:10:29

US3472020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User entered 'bpm'	System	07 Oct 2020 18:10:29

US3472020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:57:19
User entered '12'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:10:29

US3472020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User entered 'breaths/min'	System	07 Oct 2020 18:10:29

US3472020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:57:19
User entered '105'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:10:29

US3472020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User entered 'mmHg'	System	07 Oct 2020 18:10:29

US3472020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:57:19
User entered '74'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:10:29

US3472020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User entered 'mmHg'	System	07 Oct 2020 18:10:29

US3472020

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:45:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:57:24
User entered 'Yes (Y)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:10:38

US3472020

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:45:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:57:24
User entered '7 Oct 2020'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:10:38

US3472020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:45:01

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:57:30
User entered 'Yes (Y)'	Christopher Chianese (b) (4)	07 Oct 2020 16:03:53

US3472020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:45:01

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:57:30
User entered empty.	Christopher Chianese (b) (4)	07 Oct 2020 16:03:53

US3472020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:45:01

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)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:57:30
User entered empty.	Christopher Chianese (b) (4)	07 Oct 2020 16:03:53

US3472020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:45:01

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User entered 'MRNA-1273 OR PLACEBO'	System	07 Oct 2020 16:03:53

US3472020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:45:01

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:57:30
User entered '7 Oct 2020'	Christopher Chianese (b) (4)	07 Oct 2020 16:03:53

US3472020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:57:30
User entered '12:00'	Christopher Chianese (b) (4)	07 Oct 2020 16:03:53

US3472020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User entered '7 Oct 2020 12:00'	System	07 Oct 2020 16:03:53

US3472020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:57:30
User entered 'Right Arm (RIGHT ARM)'	Christopher Chianese (b) (4)	07 Oct 2020 16:03:53

US3472020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 14:57:30
User entered 'ONCE'	System	07 Oct 2020 16:03:53

US3472020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:45:01

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User entered 'INTRAMUSCULAR'	System	07 Oct 2020 16:03:53

US3472020

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:45:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:57:34
User entered 'Yes (Y)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:11:10

US3472020

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:45:01

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:57:34
User entered '7 Oct 2020'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:11:10

US3472020

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:45:01

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:57:34
User entered '11:30'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:11:10

US3472020

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User entered '7 Oct 2020 11:30'	System	07 Oct 2020 18:11:10

US3472020

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:45:01

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:57:39
User entered '7 Oct 2020'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:11:24

US3472020

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:45:01

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:11:24

US3472020

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:45:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:57:39
User entered 'Yes (Y)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:11:24

US3472020

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:45:01

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:57:39
User entered '11:35'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:11:24

US3472020

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User entered '7 Oct 2020 11:35'	System	07 Oct 2020 18:11:24

US3472020

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:45:01

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:11:24

US3472020

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:45:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:57:39
User entered 'No (N)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:11:24

US3472020

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:45:01

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:57:39
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:11:24

US3472020

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User entered empty.	System	07 Oct 2020 18:11:24

US3472020

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:57:45
User entered 'Yes (Y)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:12:59

US3472020

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User entered '1'	System	07 Oct 2020 18:12:59

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
Data entry locked.	System	07 Oct 2020 16:03:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:45:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-07T12:24:03', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'f0173705-988b-4315-a53c-d15d36252e66'	System	07 Oct 2020 16:24:19
User entered 'Yes (Y)'	System	07 Oct 2020 16:24:19

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:45:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-07T12:24:08', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'f0173705-988b-4315-a53c-d15d36252e66'	System	07 Oct 2020 16:24:19
User entered '97.5'	System	07 Oct 2020 16:24:19

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-07T12:24:12', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'f0173705-988b-4315-a53c-d15d36252e66'	System	07 Oct 2020 16:24:19
User entered 'No (N)'	System	07 Oct 2020 16:24:19

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:45:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-07T12:24:17', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'f0173705-988b-4315-a53c-d15d36252e66'	System	07 Oct 2020 16:24:19
User entered '07 Oct 2020 12:24'	System	07 Oct 2020 16:24:19

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:45:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '07 Oct 2020 12:20'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:45:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '07 Oct 2020 14:50'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
Data entry locked.	System	07 Oct 2020 16:03:53
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-07T19:45:31', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'b0407dc3-e089-4f86-a28c-9a2bc8723a09'	System	07 Oct 2020 23:45:50
User entered 'Yes (Y)'	System	07 Oct 2020 23:45:50

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-07T19:45:38', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'b0407dc3-e089-4f86-a28c-9a2bc8723a09'	System	07 Oct 2020 23:45:50
User entered '97.9'	System	07 Oct 2020 23:45:50

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-07T19:45:42', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'b0407dc3-e089-4f86-a28c-9a2bc8723a09'	System	07 Oct 2020 23:45:50
User entered 'No (N)'	System	07 Oct 2020 23:45:50

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-07T19:45:48', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'b0407dc3-e089-4f86-a28c-9a2bc8723a09'	System	07 Oct 2020 23:45:50
User entered '07 Oct 2020 19:45'	System	07 Oct 2020 23:45:50

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '07 Oct 2020 15:45'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
Data entry locked.	System	07 Oct 2020 16:03:53
User entered 'Day 2'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:45:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-08T19:36:18', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'ab895239-c44f-4ddf-ba97-04c1587f323c'	System	08 Oct 2020 23:36:45
User entered 'Yes (Y)'	System	08 Oct 2020 23:36:45

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:45:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-08T19:36:28', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'ab895239-c44f-4ddf-ba97-04c1587f323c'	System	08 Oct 2020 23:36:45
User entered '97.9'	System	08 Oct 2020 23:36:45

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-08T19:36:32', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'ab895239-c44f-4ddf-ba97-04c1587f323c'	System	08 Oct 2020 23:36:45
User entered 'No (N)'	System	08 Oct 2020 23:36:45

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:45:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-08T19:36:41', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'ab895239-c44f-4ddf-ba97-04c1587f323c'	System	08 Oct 2020 23:36:45
User entered '08 Oct 2020 19:36'	System	08 Oct 2020 23:36:45

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:45:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:45:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
Data entry locked.	System	07 Oct 2020 16:03:53
User entered 'Day 3'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:45:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-09T18:56:04', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'd8b93007-2b29-46c4-a96c-a4760409d02b'	System	09 Oct 2020 22:56:23
User entered 'Yes (Y)'	System	09 Oct 2020 22:56:23

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:45:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-09T18:56:11', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'd8b93007-2b29-46c4-a96c-a4760409d02b'	System	09 Oct 2020 22:56:23
User entered '97.9'	System	09 Oct 2020 22:56:23

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-09T18:56:14', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'd8b93007-2b29-46c4-a96c-a4760409d02b'	System	09 Oct 2020 22:56:23
User entered 'No (N)'	System	09 Oct 2020 22:56:23

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:45:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-09T18:56:17', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'd8b93007-2b29-46c4-a96c-a4760409d02b'	System	09 Oct 2020 22:56:23
User entered '09 Oct 2020 18:56'	System	09 Oct 2020 22:56:23

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:45:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:45:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
Data entry locked.	System	07 Oct 2020 16:03:53
User entered 'Day 4'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:45:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-10T20:32:44', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'bcc1eab1-ea8f-4896-868a-8ea89c36eb5a'	System	11 Oct 2020 00:33:07
User entered 'Yes (Y)'	System	11 Oct 2020 00:33:07

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:45:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-10T20:32:56', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'bcc1eab1-ea8f-4896-868a-8ea89c36eb5a'	System	11 Oct 2020 00:33:07
User entered '98.0'	System	11 Oct 2020 00:33:07

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-10T20:32:59', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'bcc1eab1-ea8f-4896-868a-8ea89c36eb5a'	System	11 Oct 2020 00:33:07
User entered 'No (N)'	System	11 Oct 2020 00:33:07

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:45:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-10T20:33:04', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'bcc1eab1-ea8f-4896-868a-8ea89c36eb5a'	System	11 Oct 2020 00:33:07
User entered '10 Oct 2020 20:33'	System	11 Oct 2020 00:33:07

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:45:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:45:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
Data entry locked.	System	07 Oct 2020 16:03:53
User entered 'Day 5'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:45:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-11T18:22:06', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'e9ad2e46-5fbf-4d19-ad83-3e578e69fbb3'	System	11 Oct 2020 22:22:34
User entered 'Yes (Y)'	System	11 Oct 2020 22:22:34

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:45:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-11T18:22:17', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'e9ad2e46-5fbf-4d19-ad83-3e578e69fbb3'	System	11 Oct 2020 22:22:34
User entered '98.6'	System	11 Oct 2020 22:22:34

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-11T18:22:25', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'e9ad2e46-5fbf-4d19-ad83-3e578e69fbb3'	System	11 Oct 2020 22:22:34
User entered 'No (N)'	System	11 Oct 2020 22:22:34

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:45:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-11T18:22:29', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'e9ad2e46-5fbf-4d19-ad83-3e578e69fbb3'	System	11 Oct 2020 22:22:34
User entered '11 Oct 2020 18:22'	System	11 Oct 2020 22:22:34

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:45:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:45:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
Data entry locked.	System	07 Oct 2020 16:03:53
User entered 'Day 6'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:45:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-12T21:42:04', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'abae2172-4d46-4c80-b073-f9ce07279659'	System	13 Oct 2020 01:42:20
User entered 'Yes (Y)'	System	13 Oct 2020 01:42:20

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:45:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-12T21:42:10', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'abae2172-4d46-4c80-b073-f9ce07279659'	System	13 Oct 2020 01:42:20
User entered '98.0'	System	13 Oct 2020 01:42:20

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-12T21:42:13', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'abae2172-4d46-4c80-b073-f9ce07279659'	System	13 Oct 2020 01:42:20
User entered 'No (N)'	System	13 Oct 2020 01:42:20

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:45:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-12T21:42:19', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'abae2172-4d46-4c80-b073-f9ce07279659' User entered '12 Oct 2020 21:42'	System	13 Oct 2020 01:42:20
	System	13 Oct 2020 01:42:20

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:45:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:45:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
Data entry locked.	System	07 Oct 2020 16:03:53
User entered 'Day 7'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:45:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-14T10:14:38', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '71a5bfca-6c59-4337-9371-2a1dfd18e9cf' User entered 'No (N)'	System	14 Oct 2020 14:14:50
	System	14 Oct 2020 14:14:50

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-14T10:14:42', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '71a5bfca-6c59-4337-9371-2a1dfd18e9cf'	System	14 Oct 2020 14:14:50
User entered 'No (N)'	System	14 Oct 2020 14:14:50

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:45:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-14T10:14:46', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '71a5bfca-6c59-4337-9371-2a1dfd18e9cf' User entered '14 Oct 2020 10:14'	System	14 Oct 2020 14:14:50
	System	14 Oct 2020 14:14:50

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:45:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:45:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
Data entry locked.	System	07 Oct 2020 16:03:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:45:01

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 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-07T12:24:40', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'f20f9df6-40a4-45e1-8a68-d028c2794ab6'	System	07 Oct 2020 16:25:46
User entered 'None (1)'	System	07 Oct 2020 16:25:46

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-07T12:25:08', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'f20f9df6-40a4-45e1-8a68-d028c2794ab6'	System	07 Oct 2020 16:25:46
User entered 'No (N)'	System	07 Oct 2020 16:25:46

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-07T12:25:15', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'f20f9df6-40a4-45e1-8a68-d028c2794ab6'	System	07 Oct 2020 16:25:46
User entered 'No (N)'	System	07 Oct 2020 16:25:46

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:45:01

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 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-07T12:25:26', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'f20f9df6-40a4-45e1-8a68-d028c2794ab6'	System	07 Oct 2020 16:25:46
User entered 'None (1)'	System	07 Oct 2020 16:25:46

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:45:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-07T12:25:43', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'f20f9df6-40a4-45e1-8a68-d028c2794ab6'	System	07 Oct 2020 16:25:46
User entered '07 Oct 2020 12:25'	System	07 Oct 2020 16:25:46

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:45:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '07 Oct 2020 12:20'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:45:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '07 Oct 2020 14:50'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
Data entry locked.	System	07 Oct 2020 16:03:53
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

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 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-07T19:45:58', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '0030ea33-be69-4b1d-bba6-e9932207485e'	System	07 Oct 2020 23:46:26
User entered 'None (1)'	System	07 Oct 2020 23:46:26

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-07T19:46:01', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '0030ea33-be69-4b1d-bba6-e9932207485e'	System	07 Oct 2020 23:46:26
User entered 'No (N)'	System	07 Oct 2020 23:46:26

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-07T19:46:04', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '0030ea33-be69-4b1d-bba6-e9932207485e'	System	07 Oct 2020 23:46:26
User entered 'No (N)'	System	07 Oct 2020 23:46:26

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

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 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-07T19:46:17', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '0030ea33-be69-4b1d-bba6-e9932207485e'	System	07 Oct 2020 23:46:26
User entered 'None (1)'	System	07 Oct 2020 23:46:26

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-07T19:46:22', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '0030ea33-be69-4b1d-bba6-e9932207485e' User entered '07 Oct 2020 19:46'	System	07 Oct 2020 23:46:26
	System	07 Oct 2020 23:46:26

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '07 Oct 2020 15:45'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
Data entry locked.	System	07 Oct 2020 16:03:53
User entered 'Day 2'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:45:01

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 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-08T19:37:12', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'ff0fb594-b9a5-4be0-a90b-c3f8156e1a84'	System	08 Oct 2020 23:38:07
User entered 'None (1)'	System	08 Oct 2020 23:38:07

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-08T19:37:23', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'ff0fb594-b9a5-4be0-a90b-c3f8156e1a84'	System	08 Oct 2020 23:38:07
User entered 'No (N)'	System	08 Oct 2020 23:38:07

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-08T19:37:26', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'ff0fb594-b9a5-4be0-a90b-c3f8156e1a84'	System	08 Oct 2020 23:38:07
User entered 'No (N)'	System	08 Oct 2020 23:38:07

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:45:01

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 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-08T19:37:51', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'ff0fb594-b9a5-4be0-a90b-c3f8156e1a84'	System	08 Oct 2020 23:38:07
User entered 'None (1)'	System	08 Oct 2020 23:38:07

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:45:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-08T19:38:02', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'ff0fb594-b9a5-4be0-a90b-c3f8156e1a84'	System	08 Oct 2020 23:38:07
User entered '08 Oct 2020 19:38'	System	08 Oct 2020 23:38:07

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:45:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:45:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
Data entry locked.	System	07 Oct 2020 16:03:53
User entered 'Day 3'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:45:01

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 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-09T18:56:49', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'd0aee155-e9a2-42c7-9dab-8561bb796a8f'	System	09 Oct 2020 22:57:15
User entered 'None (1)'	System	09 Oct 2020 22:57:15

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-09T18:56:55', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'd0aee155-e9a2-42c7-9dab-8561bb796a8f'	System	09 Oct 2020 22:57:15
User entered 'No (N)'	System	09 Oct 2020 22:57:15

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-09T18:56:57', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'd0aee155-e9a2-42c7-9dab-8561bb796a8f'	System	09 Oct 2020 22:57:15
User entered 'No (N)'	System	09 Oct 2020 22:57:15

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:45:01

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 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-09T18:57:07', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'd0aee155-e9a2-42c7-9dab-8561bb796a8f'	System	09 Oct 2020 22:57:15
User entered 'None (1)'	System	09 Oct 2020 22:57:15

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:45:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-09T18:57:13', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'd0aee155-e9a2-42c7-9dab-8561bb796a8f' User entered '09 Oct 2020 18:57'	System	09 Oct 2020 22:57:15
	System	09 Oct 2020 22:57:15

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:45:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:45:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
Data entry locked.	System	07 Oct 2020 16:03:53
User entered 'Day 4'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:45:01

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 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-10T20:33:30', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'b42a9c7e-7dd5-4711-a345-cc8349d677f4'	System	11 Oct 2020 00:33:50
User entered 'None (1)'	System	11 Oct 2020 00:33:50

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-10T20:33:33', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'b42a9c7e-7dd5-4711-a345-cc8349d677f4'	System	11 Oct 2020 00:33:50
User entered 'No (N)'	System	11 Oct 2020 00:33:50

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-10T20:33:35', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'b42a9c7e-7dd5-4711-a345-cc8349d677f4'	System	11 Oct 2020 00:33:50
User entered 'No (N)'	System	11 Oct 2020 00:33:50

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:45:01

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 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-10T20:33:44', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'b42a9c7e-7dd5-4711-a345-cc8349d677f4'	System	11 Oct 2020 00:33:50
User entered 'None (1)'	System	11 Oct 2020 00:33:50

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:45:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-10T20:33:49', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'b42a9c7e-7dd5-4711-a345-cc8349d677f4'	System	11 Oct 2020 00:33:50
User entered '10 Oct 2020 20:33'	System	11 Oct 2020 00:33:50

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:45:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:45:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
Data entry locked.	System	07 Oct 2020 16:03:53
User entered 'Day 5'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:45:01

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 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-11T18:22:33', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '7cbdcca1-e31a-45f0-a328-5c2fcf5078be'	System	11 Oct 2020 22:22:51
User entered 'None (1)'	System	11 Oct 2020 22:22:51

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-11T18:22:36', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '7cbdcca1-e31a-45f0-a328-5c2fcf5078be'	System	11 Oct 2020 22:22:51
User entered 'No (N)'	System	11 Oct 2020 22:22:51

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-11T18:22:39', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '7cbdcca1-e31a-45f0-a328-5c2fcf5078be'	System	11 Oct 2020 22:22:51
User entered 'No (N)'	System	11 Oct 2020 22:22:51

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:45:01

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 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-11T18:22:42', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '7cbdcca1-e31a-45f0-a328-5c2fcf5078be'	System	11 Oct 2020 22:22:51
User entered 'None (1)'	System	11 Oct 2020 22:22:51

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:45:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-11T18:22:46', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '7cbdcca1-e31a-45f0-a328-5c2fcf5078be'	System	11 Oct 2020 22:22:51
User entered '11 Oct 2020 18:22'	System	11 Oct 2020 22:22:51

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:45:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:45:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
Data entry locked.	System	07 Oct 2020 16:03:53
User entered 'Day 6'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:45:01

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 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-12T21:42:24', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '841b9f0c-455d-4780-a8c8-20679f2a34f3'	System	13 Oct 2020 01:42:49
User entered 'None (1)'	System	13 Oct 2020 01:42:49

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-12T21:42:28', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '841b9f0c-455d-4780-a8c8-20679f2a34f3'	System	13 Oct 2020 01:42:49
User entered 'No (N)'	System	13 Oct 2020 01:42:49

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-12T21:42:30', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '841b9f0c-455d-4780-a8c8-20679f2a34f3'	System	13 Oct 2020 01:42:49
User entered 'No (N)'	System	13 Oct 2020 01:42:49

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:45:01

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 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-12T21:42:39', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '841b9f0c-455d-4780-a8c8-20679f2a34f3'	System	13 Oct 2020 01:42:49
User entered 'None (1)'	System	13 Oct 2020 01:42:49

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:45:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-12T21:42:45', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '841b9f0c-455d-4780-a8c8-20679f2a34f3'	System	13 Oct 2020 01:42:49
User entered '12 Oct 2020 21:42'	System	13 Oct 2020 01:42:49

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:45:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:45:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
Data entry locked.	System	07 Oct 2020 16:03:53
User entered 'Day 7'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:45:01

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 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-14T10:14:49', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '12fdbbc2d-c440-436b-9c6c-bc84cbc98367'	System	14 Oct 2020 14:15:05
User entered 'None (1)'	System	14 Oct 2020 14:15:05

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-14T10:14:51', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '12fdb2d-c440-436b-9c6c-bc84cbc98367'	System	14 Oct 2020 14:15:05
User entered 'No (N)'	System	14 Oct 2020 14:15:05

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-14T10:14:55', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '12fdb2d-c440-436b-9c6c-bc84cbc98367'	System	14 Oct 2020 14:15:05
User entered 'No (N)'	System	14 Oct 2020 14:15:05

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:45:01

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 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-14T10:14:57', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '12fdbbc2d-c440-436b-9c6c-bc84cbc98367'	System	14 Oct 2020 14:15:05
User entered 'None (1)'	System	14 Oct 2020 14:15:05

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:45:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-14T10:15:01', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '12fdb2d-c440-436b-9c6c-bc84cbc98367'	System	14 Oct 2020 14:15:05
User entered '14 Oct 2020 10:15'	System	14 Oct 2020 14:15:05

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:45:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:45:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
Data entry locked.	System	07 Oct 2020 16:03:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:45:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-07T12:25:49', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'c5377432-84b2-4f9d-98fb-f05335fbf5eb'	System	07 Oct 2020 16:26:46
User entered 'None (0)'	System	07 Oct 2020 16:26:46

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:45:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-07T12:25:53', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'c5377432-84b2-4f9d-98fb-f05335fbf5eb'	System	07 Oct 2020 16:26:46
User entered 'None (0)'	System	07 Oct 2020 16:26:46

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:45:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-07T12:25:57', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'c5377432-84b2-4f9d-98fb-f05335fbf5eb'	System	07 Oct 2020 16:26:46
User entered 'None (0)'	System	07 Oct 2020 16:26:46

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:45:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-07T12:26:01', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'c5377432-84b2-4f9d-98fb-f05335fbf5eb'	System	07 Oct 2020 16:26:46
User entered 'None (0)'	System	07 Oct 2020 16:26:46

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:45:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-07T12:26:07', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'c5377432-84b2-4f9d-98fb-f05335fbf5eb'	System	07 Oct 2020 16:26:46
User entered 'None (0)'	System	07 Oct 2020 16:26:46

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:45:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-07T12:26:23', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'c5377432-84b2-4f9d-98fb-f05335fbf5eb'	System	07 Oct 2020 16:26:46
User entered 'None (0)'	System	07 Oct 2020 16:26:46

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:45:01

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 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-07T12:26:33', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'c5377432-84b2-4f9d-98fb-f05335fbf5eb'	System	07 Oct 2020 16:26:46
User entered 'No (N)'	System	07 Oct 2020 16:26:46

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:45:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-07T12:26:37', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'c5377432-84b2-4f9d-98fb-f05335fbf5eb' User entered '07 Oct 2020 12:26'	System	07 Oct 2020 16:26:46
	System	07 Oct 2020 16:26:46

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:45:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '07 Oct 2020 12:20'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:45:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '07 Oct 2020 14:50'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
Data entry locked.	System	07 Oct 2020 16:03:53
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-07T19:46:33', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '1395e3ea-525a-4bdc-b999-d2c90dca53a6'	System	07 Oct 2020 23:47:37
User entered 'None (0)'	System	07 Oct 2020 23:47:37

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-07T19:46:36', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '1395e3ea-525a-4bdc-b999-d2c90dca53a6'	System	07 Oct 2020 23:47:37
User entered 'None (0)'	System	07 Oct 2020 23:47:37

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-07T19:46:39', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '1395e3ea-525a-4bdc-b999-d2c90dca53a6'	System	07 Oct 2020 23:47:37
User entered 'None (0)'	System	07 Oct 2020 23:47:37

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-07T19:46:44', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '1395e3ea-525a-4bdc-b999-d2c90dca53a6'	System	07 Oct 2020 23:47:37
User entered 'None (0)'	System	07 Oct 2020 23:47:37

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-07T19:47:15', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '1395e3ea-525a-4bdc-b999-d2c90dca53a6'	System	07 Oct 2020 23:47:37
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	07 Oct 2020 23:47:37

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-07T19:47:19', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '1395e3ea-525a-4bdc-b999-d2c90dca53a6'	System	07 Oct 2020 23:47:37
User entered 'None (0)'	System	07 Oct 2020 23:47:37

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

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 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-07T19:47:22', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '1395e3ea-525a-4bdc-b999-d2c90dca53a6'	System	07 Oct 2020 23:47:37
User entered 'No (N)'	System	07 Oct 2020 23:47:37

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-07T19:47:34', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '1395e3ea-525a-4bdc-b999-d2c90dca53a6' User entered '07 Oct 2020 19:47'	System	07 Oct 2020 23:47:37
	System	07 Oct 2020 23:47:37

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '07 Oct 2020 15:45'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:45:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
Data entry locked.	System	07 Oct 2020 16:03:53
User entered 'Day 2'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:45:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-08T19:38:11', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'd4307892-69ec-46ce-ab20-2f29d981f8d4'	System	08 Oct 2020 23:39:56
User entered 'None (0)'	System	08 Oct 2020 23:39:56

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:45:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-08T19:38:16', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'd4307892-69ec-46ce-ab20-2f29d981f8d4'	System	08 Oct 2020 23:39:56
User entered 'Some interference with activity (2)'	System	08 Oct 2020 23:39:56

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:45:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-08T19:38:19', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'd4307892-69ec-46ce-ab20-2f29d981f8d4'	System	08 Oct 2020 23:39:56
User entered 'Some interference with activity (2)'	System	08 Oct 2020 23:39:56

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:45:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-08T19:38:27', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'd4307892-69ec-46ce-ab20-2f29d981f8d4'	System	08 Oct 2020 23:39:56
User entered 'None (0)'	System	08 Oct 2020 23:39:56

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:45:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-08T19:39:36', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'd4307892-69ec-46ce-ab20-2f29d981f8d4'	System	08 Oct 2020 23:39:56
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	08 Oct 2020 23:39:56

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:45:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-08T19:38:40', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'd4307892-69ec-46ce-ab20-2f29d981f8d4'	System	08 Oct 2020 23:39:56
User entered 'Some interference with activity not requiring medical attention (2)'	System	08 Oct 2020 23:39:56

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:45:01

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 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-08T19:38:58', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'd4307892-69ec-46ce-ab20-2f29d981f8d4'	System	08 Oct 2020 23:39:56
User entered 'No (N)'	System	08 Oct 2020 23:39:56

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:45:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-08T19:39:54', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'd4307892-69ec-46ce-ab20-2f29d981f8d4'	System	08 Oct 2020 23:39:56
User entered '08 Oct 2020 19:39'	System	08 Oct 2020 23:39:56

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:45:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:45:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
Data entry locked.	System	07 Oct 2020 16:03:53
User entered 'Day 3'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:45:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-09T18:57:19', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '5dd4566a-06cd-4afd-8f97-7a83ec8ff4c3'	System	09 Oct 2020 22:57:49
User entered 'None (0)'	System	09 Oct 2020 22:57:49

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:45:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-09T18:57:25', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '5dd4566a-06cd-4afd-8f97-7a83ec8ff4c3'	System	09 Oct 2020 22:57:49
User entered 'None (0)'	System	09 Oct 2020 22:57:49

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:45:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-09T18:57:27', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '5dd4566a-06cd-4afd-8f97-7a83ec8ff4c3'	System	09 Oct 2020 22:57:49
User entered 'None (0)'	System	09 Oct 2020 22:57:49

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:45:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-09T18:57:31', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '5dd4566a-06cd-4afd-8f97-7a83ec8ff4c3'	System	09 Oct 2020 22:57:49
User entered 'None (0)'	System	09 Oct 2020 22:57:49

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:45:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-09T18:57:33', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '5dd4566a-06cd-4afd-8f97-7a83ec8ff4c3'	System	09 Oct 2020 22:57:49
User entered 'None (0)'	System	09 Oct 2020 22:57:49

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:45:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-09T18:57:36', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '5dd4566a-06cd-4afd-8f97-7a83ec8ff4c3'	System	09 Oct 2020 22:57:49
User entered 'No interference with activity (1)'	System	09 Oct 2020 22:57:49

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:45:01

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 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-09T18:57:39', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '5dd4566a-06cd-4afd-8f97-7a83ec8ff4c3'	System	09 Oct 2020 22:57:49
User entered 'No (N)'	System	09 Oct 2020 22:57:49

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:45:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-09T18:57:47', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '5dd4566a-06cd-4afd-8f97-7a83ec8ff4c3'	System	09 Oct 2020 22:57:49
User entered '09 Oct 2020 18:57'	System	09 Oct 2020 22:57:49

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:45:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:45:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
Data entry locked.	System	07 Oct 2020 16:03:53
User entered 'Day 4'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:45:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-10T20:33:53', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '6daceb96-62b8-4e79-bda1-f9e7b350645b'	System	11 Oct 2020 00:34:40
User entered 'None (0)'	System	11 Oct 2020 00:34:40

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:45:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-10T20:33:57', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '6daceb96-62b8-4e79-bda1-f9e7b350645b'	System	11 Oct 2020 00:34:40
User entered 'None (0)'	System	11 Oct 2020 00:34:40

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:45:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-10T20:34:00', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '6daceb96-62b8-4e79-bda1-f9e7b350645b'	System	11 Oct 2020 00:34:40
User entered 'None (0)'	System	11 Oct 2020 00:34:40

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:45:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-10T20:34:02', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '6daceb96-62b8-4e79-bda1-f9e7b350645b'	System	11 Oct 2020 00:34:40
User entered 'None (0)'	System	11 Oct 2020 00:34:40

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:45:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-10T20:34:16', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '6daceb96-62b8-4e79-bda1-f9e7b350645b'	System	11 Oct 2020 00:34:40
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	11 Oct 2020 00:34:40

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:45:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-10T20:34:25', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '6daceb96-62b8-4e79-bda1-f9e7b350645b'	System	11 Oct 2020 00:34:40
User entered 'No interference with activity (1)'	System	11 Oct 2020 00:34:40

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:45:01

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 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-10T20:34:28', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '6daceb96-62b8-4e79-bda1-f9e7b350645b'	System	11 Oct 2020 00:34:40
User entered 'No (N)'	System	11 Oct 2020 00:34:40

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:45:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-10T20:34:37', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '6daceb96-62b8-4e79-bda1-f9e7b350645b'	System	11 Oct 2020 00:34:40
User entered '10 Oct 2020 20:34'	System	11 Oct 2020 00:34:40

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:45:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:45:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
Data entry locked.	System	07 Oct 2020 16:03:53
User entered 'Day 5'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:45:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-11T18:22:50', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '40004aa7-b899-4bf9-9627-b362c608ef40'	System	11 Oct 2020 22:23:14
User entered 'None (0)'	System	11 Oct 2020 22:23:14

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:45:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-11T18:22:52', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '40004aa7-b899-4bf9-9627-b362c608ef40'	System	11 Oct 2020 22:23:14
User entered 'None (0)'	System	11 Oct 2020 22:23:14

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:45:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-11T18:22:54', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '40004aa7-b899-4bf9-9627-b362c608ef40'	System	11 Oct 2020 22:23:14
User entered 'None (0)'	System	11 Oct 2020 22:23:14

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:45:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-11T18:22:56', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '40004aa7-b899-4bf9-9627-b362c608ef40'	System	11 Oct 2020 22:23:14
User entered 'None (0)'	System	11 Oct 2020 22:23:14

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:45:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-11T18:22:58', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '40004aa7-b899-4bf9-9627-b362c608ef40'	System	11 Oct 2020 22:23:14
User entered 'None (0)'	System	11 Oct 2020 22:23:14

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:45:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-11T18:23:01', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '40004aa7-b899-4bf9-9627-b362c608ef40'	System	11 Oct 2020 22:23:14
User entered 'None (0)'	System	11 Oct 2020 22:23:14

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:45:01

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 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-11T18:23:05', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '40004aa7-b899-4bf9-9627-b362c608ef40'	System	11 Oct 2020 22:23:14
User entered 'No (N)'	System	11 Oct 2020 22:23:14

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:45:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-11T18:23:10', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '40004aa7-b899-4bf9-9627-b362c608ef40'	System	11 Oct 2020 22:23:14
User entered '11 Oct 2020 18:23'	System	11 Oct 2020 22:23:14

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:45:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:45:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
Data entry locked.	System	07 Oct 2020 16:03:53
User entered 'Day 6'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:45:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-12T21:42:49', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'a35ae352-92b7-476f-9d4f-89701e402977'	System	13 Oct 2020 01:43:12
User entered 'None (0)'	System	13 Oct 2020 01:43:12

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:45:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-12T21:42:51', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'a35ae352-92b7-476f-9d4f-89701e402977'	System	13 Oct 2020 01:43:12
User entered 'None (0)'	System	13 Oct 2020 01:43:12

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:45:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-12T21:42:54', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'a35ae352-92b7-476f-9d4f-89701e402977'	System	13 Oct 2020 01:43:12
User entered 'None (0)'	System	13 Oct 2020 01:43:12

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:45:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-12T21:42:57', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'a35ae352-92b7-476f-9d4f-89701e402977'	System	13 Oct 2020 01:43:12
User entered 'None (0)'	System	13 Oct 2020 01:43:12

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:45:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-12T21:42:59', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'a35ae352-92b7-476f-9d4f-89701e402977'	System	13 Oct 2020 01:43:12
User entered 'None (0)'	System	13 Oct 2020 01:43:12

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:45:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-12T21:43:03', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'a35ae352-92b7-476f-9d4f-89701e402977'	System	13 Oct 2020 01:43:12
User entered 'None (0)'	System	13 Oct 2020 01:43:12

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:45:01

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 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-12T21:43:06', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'a35ae352-92b7-476f-9d4f-89701e402977'	System	13 Oct 2020 01:43:12
User entered 'No (N)'	System	13 Oct 2020 01:43:12

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:45:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-12T21:43:11', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'a35ae352-92b7-476f-9d4f-89701e402977'	System	13 Oct 2020 01:43:12
User entered '12 Oct 2020 21:43'	System	13 Oct 2020 01:43:12

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:45:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:45:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
Data entry locked.	System	07 Oct 2020 16:03:53
User entered 'Day 7'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:45:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-14T10:15:06', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'b4a44955-080d-4e14-aa6b-6cdd21077e32'	System	14 Oct 2020 14:15:28
User entered 'None (0)'	System	14 Oct 2020 14:15:28

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:45:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-14T10:15:08', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'b4a44955-080d-4e14-aa6b-6cdd21077e32'	System	14 Oct 2020 14:15:28
User entered 'None (0)'	System	14 Oct 2020 14:15:28

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:45:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-14T10:15:12', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'b4a44955-080d-4e14-aa6b-6cdd21077e32'	System	14 Oct 2020 14:15:28
User entered 'None (0)'	System	14 Oct 2020 14:15:28

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:45:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-14T10:15:15', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'b4a44955-080d-4e14-aa6b-6cdd21077e32'	System	14 Oct 2020 14:15:28
User entered 'None (0)'	System	14 Oct 2020 14:15:28

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:45:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-14T10:15:17', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'b4a44955-080d-4e14-aa6b-6cdd21077e32'	System	14 Oct 2020 14:15:28
User entered 'None (0)'	System	14 Oct 2020 14:15:28

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:45:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-14T10:15:19', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'b4a44955-080d-4e14-aa6b-6cdd21077e32'	System	14 Oct 2020 14:15:28
User entered 'None (0)'	System	14 Oct 2020 14:15:28

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:45:01

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 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-14T10:15:21', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'b4a44955-080d-4e14-aa6b-6cdd21077e32'	System	14 Oct 2020 14:15:28
User entered 'No (N)'	System	14 Oct 2020 14:15:28

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:45:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-10-14T10:15:24', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'b4a44955-080d-4e14-aa6b-6cdd21077e32'	System	14 Oct 2020 14:15:28
User entered '14 Oct 2020 10:15'	System	14 Oct 2020 14:15:28

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:45:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 16:03:53

US3472020

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:45:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 16:03:53

US3472020

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:56:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 18:51:47

US3472020

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:56:38
User entered '14 Oct 2020'		14 Oct 2020 18:51:47

US3472020

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:56:38
User entered 'Contact Made (CONTACT MADE)'		14 Oct 2020 18:51:47

US3472020

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:56:38
User entered empty.		14 Oct 2020 18:51:47

US3472020

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:56:42
User entered 'Yes (Y)'		14 Oct 2020 18:51:52

US3472020

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User entered '1'	System	14 Oct 2020 18:51:52

US3472020

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:59:22
User entered 'Yes (Y)'		21 Oct 2020 19:04:58

US3472020

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:59:22
User entered '21 Oct 2020'		21 Oct 2020 19:04:58

US3472020

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:59:22
User entered 'Contact Made (CONTACT MADE)'		21 Oct 2020 19:04:58

US3472020

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:59:22
User entered empty.		21 Oct 2020 19:04:58

US3472020

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:59:26
User entered 'Yes (Y)'		21 Oct 2020 19:05:01

US3472020

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User entered '1'	System	21 Oct 2020 19:05:01

US3472020

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:59:31
User entered 'Yes (Y)'	Debora Dunbar (b) (4) (b) (4)	01 Nov 2020 15:11:52

US3472020

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:59:31
User entered '31 Oct 2020'	Debora Dunbar (b) (4) (b) (4)	01 Nov 2020 15:11:52

US3472020

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:59:31
User entered 'Contact Made (CONTACT MADE)'	Debora Dunbar (b) (4) (b) (4)	01 Nov 2020 15:11:52

US3472020

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:59:31
User entered empty.	Debora Dunbar (b) (4) (b) (4)	01 Nov 2020 15:11:52

US3472020

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:59:37
User entered 'Yes (Y)'	Debora Dunbar (b) (4) (b) (4)	01 Nov 2020 15:12:21

US3472020

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User entered '1'	System	01 Nov 2020 15:12:21

US3472020

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:45:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:18
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:58:59
User entered 'Yes (Y)'		05 Nov 2020 01:25:15

US3472020

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:18
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:58:59
User entered '4 Nov 2020'		05 Nov 2020 01:25:15

US3472020

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:18
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:58:59
User entered 'Clinic (Clinic)'		05 Nov 2020 01:25:15

US3472020

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:45:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:18
User entered 'VISIT3'	System	05 Nov 2020 01:25:15

US3472020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:18
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:59:03
User entered 'Yes (Y)'		05 Nov 2020 01:26:28

US3472020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:18
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:59:03
User entered '04 Nov 2020'		05 Nov 2020 01:26:28

US3472020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:18
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:59:03
User entered '11:12'		05 Nov 2020 01:26:28

US3472020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:18
User entered '04 Nov 2020 11:12'	System	05 Nov 2020 01:26:28

US3472020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:18
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:59:03
User entered '36.9' C		05 Nov 2020 01:26:28

US3472020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:18
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:59:03
User closed query 'Data is required. Please provide.' (Site from System).	System	05 Nov 2020 15:54:31
Query 'Data is required. Please provide.' answered by System data change (Site from System).		05 Nov 2020 15:54:31
User entered 'Oral (Oral)' reason for change: Data Entry Error	Jie Ho (b) (4)	05 Nov 2020 15:54:31
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Nov 2020 01:26:28
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 01:26:28

US3472020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:18
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:59:03
User entered empty.		05 Nov 2020 01:26:28

US3472020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:18
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:59:03
User entered '79'		05 Nov 2020 01:26:28

US3472020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:18
User entered 'bpm'	System	05 Nov 2020 01:26:28

US3472020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:18
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:59:03
User entered '16'		05 Nov 2020 01:26:28

US3472020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:18
User entered 'breaths/min'	System	05 Nov 2020 01:26:28

US3472020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:18
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:59:03
User entered '112'		05 Nov 2020 01:26:28

US3472020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:18
User entered 'mmHg'	System	05 Nov 2020 01:26:28

US3472020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:18
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:59:03
User entered '79'		05 Nov 2020 01:26:28

US3472020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:18
User entered 'mmHg'	System	05 Nov 2020 01:26:28

US3472020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:18

US3472020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:18

US3472020

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:45:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:59:07
User entered 'Yes (Y)'		05 Nov 2020 01:27:16

US3472020

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:45:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:59:07
User entered '04 Nov 2020'		05 Nov 2020 01:27:16

US3472020

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:45:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:59:11
User entered 'Yes (Y)'		05 Nov 2020 01:27:33

US3472020

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:45:01

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:59:11
User entered '04 Nov 2020'		05 Nov 2020 01:27:33

US3472020

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:45:01

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:59:11
User entered '11:55'		05 Nov 2020 01:27:33

US3472020

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User entered '04 Nov 2020 11:55'	System	05 Nov 2020 01:27:33

US3472020

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:59:15
User entered 'Yes (Y)'		05 Nov 2020 01:27:40

US3472020

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User entered '1'	System	05 Nov 2020 01:27:40

US3472020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
Data entry locked.	System	08 Sep 2020 18:18:25
User entered 'Day 64'	System	08 Sep 2020 18:18:25

US3472020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-11-10T08:29:00', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '15dd0087-8964-40dd-924c-57e167e7f552'	System	10 Nov 2020 13:29:11
User entered 'No (N)'	System	10 Nov 2020 13:29:11

US3472020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-11-10T08:28:52', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '15dd0087-8964-40dd-924c-57e167e7f552'	System	10 Nov 2020 13:29:11
User entered 'No (N)'	System	10 Nov 2020 13:29:11

US3472020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-11-10T08:29:08', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '15dd0087-8964-40dd-924c-57e167e7f552'	System	10 Nov 2020 13:29:11
User entered '10 Nov 2020 08:29:08'	System	10 Nov 2020 13:29:11

US3472020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
Data entry locked.	System	08 Sep 2020 18:18:25
User entered '08 Nov 2020 00:01'	System	08 Sep 2020 18:18:25

US3472020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
Data entry locked.	System	08 Sep 2020 18:18:25
User entered '12 Nov 2020 23:59'	System	08 Sep 2020 18:18:25

US3472020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
Data entry locked.	System	08 Sep 2020 18:18:25
User entered 'Day 71'	System	08 Sep 2020 18:18:25

US3472020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-11-15T20:29:43', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '17a7d799-d106-4c6e-90fb-bb82586f43a0'	System	16 Nov 2020 01:30:04
User entered 'No (N)'	System	16 Nov 2020 01:30:04

US3472020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-11-15T20:29:51', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '17a7d799-d106-4c6e-90fb-bb82586f43a0'	System	16 Nov 2020 01:30:04
User entered 'No (N)'	System	16 Nov 2020 01:30:04

US3472020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-11-15T20:29:56', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '17a7d799-d106-4c6e-90fb-bb82586f43a0'	System	16 Nov 2020 01:30:04
User entered '15 Nov 2020 20:29:56'	System	16 Nov 2020 01:30:04

US3472020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
Data entry locked.	System	08 Sep 2020 18:18:25
User entered '15 Nov 2020 00:01'	System	08 Sep 2020 18:18:25

US3472020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:36
Data entry locked.	System	08 Sep 2020 18:18:25
User entered '19 Nov 2020 23:59'	System	08 Sep 2020 18:18:25

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '19 Nov 2020 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '23 Nov 2020 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[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 (3279c279ba745deb)', Time: '2020-11-27T12:42:08', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '808cce84-6d97-4e13-a8f6-1b29cc989a04'	System	27 Nov 2020 17:42:20
User entered 'No (N)'	System	27 Nov 2020 17:42:20

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

Have you been exposed to someone with 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 (3279c279ba745deb)', Time: '2020-11-27T12:42:12', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '808cce84-6d97-4e13-a8f6-1b29cc989a04'	System	27 Nov 2020 17:42:20
User entered 'No (N)'	System	27 Nov 2020 17:42:20

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-11-27T12:42:15', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '808cce84-6d97-4e13-a8f6-1b29cc989a04'	System	27 Nov 2020 17:42:20
User entered '27 Nov 2020 12:42:15'	System	27 Nov 2020 17:42:20

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '26 Nov 2020 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '30 Nov 2020 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[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 (3279c279ba745deb)', Time: '2020-12-03T16:12:29', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '63fe797e-7455-4aa9-947a-df42114f3800'	System	03 Dec 2020 21:15:09
User entered 'Yes (Y)'	System	03 Dec 2020 21:15:09

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

Have you been exposed to someone with 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 (3279c279ba745deb)', Time: '2020-12-03T16:12:38', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '63fe797e-7455-4aa9-947a-df42114f3800'	System	03 Dec 2020 21:15:09
User entered 'No (N)'	System	03 Dec 2020 21:15:09

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-12-03T16:12:44', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '63fe797e-7455-4aa9-947a-df42114f3800'	System	03 Dec 2020 21:15:09
User entered 'Yes (Y)'	System	03 Dec 2020 21:15:09

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-12-03T16:14:17', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '63fe797e-7455-4aa9-947a-df42114f3800'	System	03 Dec 2020 21:15:09
User entered '0'	System	03 Dec 2020 21:15:09

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-12-03T16:14:17', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '63fe797e-7455-4aa9-947a-df42114f3800'	System	03 Dec 2020 21:15:09
User entered '0'	System	03 Dec 2020 21:15:09

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-12-03T16:14:17', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '63fe797e-7455-4aa9-947a-df42114f3800'	System	03 Dec 2020 21:15:09
User entered '1'	System	03 Dec 2020 21:15:09

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-12-03T16:14:17', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '63fe797e-7455-4aa9-947a-df42114f3800'	System	03 Dec 2020 21:15:09
User entered '0'	System	03 Dec 2020 21:15:09

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-12-03T16:14:17', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '63fe797e-7455-4aa9-947a-df42114f3800'	System	03 Dec 2020 21:15:09
User entered '0'	System	03 Dec 2020 21:15:09

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-12-03T16:14:17', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '63fe797e-7455-4aa9-947a-df42114f3800'	System	03 Dec 2020 21:15:09
User entered '0'	System	03 Dec 2020 21:15:09

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-12-03T16:14:17', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '63fe797e-7455-4aa9-947a-df42114f3800'	System	03 Dec 2020 21:15:09
User entered '0'	System	03 Dec 2020 21:15:09

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-12-03T16:14:17', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '63fe797e-7455-4aa9-947a-df42114f3800'	System	03 Dec 2020 21:15:09
User entered '0'	System	03 Dec 2020 21:15:09

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-12-03T16:14:17', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '63fe797e-7455-4aa9-947a-df42114f3800'	System	03 Dec 2020 21:15:09
User entered '0'	System	03 Dec 2020 21:15:09

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-12-03T16:14:17', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '63fe797e-7455-4aa9-947a-df42114f3800'	System	03 Dec 2020 21:15:09
User entered '0'	System	03 Dec 2020 21:15:09

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-12-03T16:14:17', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '63fe797e-7455-4aa9-947a-df42114f3800'	System	03 Dec 2020 21:15:09
User entered '0'	System	03 Dec 2020 21:15:09

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-12-03T16:14:17', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '63fe797e-7455-4aa9-947a-df42114f3800'	System	03 Dec 2020 21:15:09
User entered '0'	System	03 Dec 2020 21:15:09

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-12-03T16:14:17', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '63fe797e-7455-4aa9-947a-df42114f3800'	System	03 Dec 2020 21:15:09
User entered '1'	System	03 Dec 2020 21:15:09

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-12-03T16:14:17', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '63fe797e-7455-4aa9-947a-df42114f3800'	System	03 Dec 2020 21:15:09
User entered '0'	System	03 Dec 2020 21:15:09

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-12-03T16:14:17', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '63fe797e-7455-4aa9-947a-df42114f3800'	System	03 Dec 2020 21:15:09
User entered '0'	System	03 Dec 2020 21:15:09

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-12-03T16:14:17', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '63fe797e-7455-4aa9-947a-df42114f3800'	System	03 Dec 2020 21:15:09
User entered '0'	System	03 Dec 2020 21:15:09

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-12-03T16:14:17', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '63fe797e-7455-4aa9-947a-df42114f3800'	System	03 Dec 2020 21:15:09
User entered '0'	System	03 Dec 2020 21:15:09

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-12-03T16:14:11', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '63fe797e-7455-4aa9-947a-df42114f3800'	System	03 Dec 2020 21:15:09
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	03 Dec 2020 21:15:09

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-12-03T16:14:26', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '63fe797e-7455-4aa9-947a-df42114f3800'	System	03 Dec 2020 21:15:09
User entered 'No (N)'	System	03 Dec 2020 21:15:09

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-12-03T16:14:57', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '63fe797e-7455-4aa9-947a-df42114f3800'	System	03 Dec 2020 21:15:09
User entered '03 Dec 2020 16:14:57'	System	03 Dec 2020 21:15:09

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '03 Dec 2020 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '07 Dec 2020 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[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 (3279c279ba745deb)', Time: '2020-12-12T15:51:21', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '90b88b8a-3cc8-49c7-aa8d-ce6c4d753413'	System	12 Dec 2020 20:51:27
User entered 'No (N)'	System	12 Dec 2020 20:51:27

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

Have you been exposed to someone with 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 (3279c279ba745deb)', Time: '2020-12-12T15:51:19', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '90b88b8a-3cc8-49c7-aa8d-ce6c4d753413'	System	12 Dec 2020 20:51:27
User entered 'No (N)'	System	12 Dec 2020 20:51:27

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-12-12T15:51:26', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '90b88b8a-3cc8-49c7-aa8d-ce6c4d753413'	System	12 Dec 2020 20:51:27
User entered '12 Dec 2020 15:51:26'	System	12 Dec 2020 20:51:27

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '10 Dec 2020 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '14 Dec 2020 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[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 (3279c279ba745deb)', Time: '2020-12-20T08:50:38', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'af1a9095-65b0-43e9-97dc-3f4d7d890b48'	System	20 Dec 2020 13:50:52
User entered 'No (N)'	System	20 Dec 2020 13:50:52

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

Have you been exposed to someone with 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 (3279c279ba745deb)', Time: '2020-12-20T08:50:43', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'af1a9095-65b0-43e9-97dc-3f4d7d890b48'	System	20 Dec 2020 13:50:52
User entered 'No (N)'	System	20 Dec 2020 13:50:52

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-12-20T08:50:48', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'af1a9095-65b0-43e9-97dc-3f4d7d890b48'	System	20 Dec 2020 13:50:52
User entered '20 Dec 2020 08:50:48'	System	20 Dec 2020 13:50:52

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '17 Dec 2020 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '21 Dec 2020 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[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 (3279c279ba745deb)', Time: '2020-12-24T18:40:42', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'ba6ac4a7-2e41-41e1-bf50-27980c77679f' User entered 'No (N)'	System	24 Dec 2020 23:40:54
	System	24 Dec 2020 23:40:54

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

Have you been exposed to someone with 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 (3279c279ba745deb)', Time: '2020-12-24T18:40:45', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'ba6ac4a7-2e41-41e1-bf50-27980c77679f'	System	24 Dec 2020 23:40:54
User entered 'No (N)'	System	24 Dec 2020 23:40:54

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2020-12-24T18:40:48', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'ba6ac4a7-2e41-41e1-bf50-27980c77679f' User entered '24 Dec 2020 18:40:48'	System	24 Dec 2020 23:40:54
	System	24 Dec 2020 23:40:54

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '24 Dec 2020 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '28 Dec 2020 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '31 Dec 2020 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '04 Jan 2021 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[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 (3279c279ba745deb)', Time: '2021-01-08T10:51:06', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'dd735889-69fe-40ed-98fc-7b967bbf6d54'	System	08 Jan 2021 15:51:18
User entered 'No (N)'	System	08 Jan 2021 15:51:18

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

Have you been exposed to someone with 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 (3279c279ba745deb)', Time: '2021-01-08T10:51:13', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'dd735889-69fe-40ed-98fc-7b967bbf6d54'	System	08 Jan 2021 15:51:18
User entered 'No (N)'	System	08 Jan 2021 15:51:18

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2021-01-08T10:51:16', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'dd735889-69fe-40ed-98fc-7b967bbf6d54'	System	08 Jan 2021 15:51:18
User entered '08 Jan 2021 10:51:16'	System	08 Jan 2021 15:51:18

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '07 Jan 2021 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '11 Jan 2021 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '14 Jan 2021 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '18 Jan 2021 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[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 (3279c279ba745deb)', Time: '2021-01-25T12:07:53', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '32ac0bd8-f5fd-42a3-8d7e-a9bdd230d451'	System	25 Jan 2021 17:10:24
User entered 'Yes (Y)'	System	25 Jan 2021 17:10:24

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

Have you been exposed to someone with 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 (3279c279ba745deb)', Time: '2021-01-25T12:08:01', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '32ac0bd8-f5fd-42a3-8d7e-a9bdd230d451'	System	25 Jan 2021 17:10:24
User entered 'No (N)'	System	25 Jan 2021 17:10:24

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2021-01-25T12:08:12', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '32ac0bd8-f5fd-42a3-8d7e-a9bdd230d451'	System	25 Jan 2021 17:10:24
User entered 'Yes (Y)'	System	25 Jan 2021 17:10:24

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2021-01-25T12:08:23', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '32ac0bd8-f5fd-42a3-8d7e-a9bdd230d451'	System	25 Jan 2021 17:10:24
User entered '0'	System	25 Jan 2021 17:10:24

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2021-01-25T12:08:23', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '32ac0bd8-f5fd-42a3-8d7e-a9bdd230d451'	System	25 Jan 2021 17:10:24
User entered '0'	System	25 Jan 2021 17:10:24

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2021-01-25T12:08:23', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '32ac0bd8-f5fd-42a3-8d7e-a9bdd230d451'	System	25 Jan 2021 17:10:24
User entered '0'	System	25 Jan 2021 17:10:24

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2021-01-25T12:08:23', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '32ac0bd8-f5fd-42a3-8d7e-a9bdd230d451'	System	25 Jan 2021 17:10:24
User entered '0'	System	25 Jan 2021 17:10:24

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2021-01-25T12:08:23', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '32ac0bd8-f5fd-42a3-8d7e-a9bdd230d451'	System	25 Jan 2021 17:10:24
User entered '0'	System	25 Jan 2021 17:10:24

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2021-01-25T12:08:23', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '32ac0bd8-f5fd-42a3-8d7e-a9bdd230d451'	System	25 Jan 2021 17:10:24
User entered '0'	System	25 Jan 2021 17:10:24

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2021-01-25T12:08:23', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '32ac0bd8-f5fd-42a3-8d7e-a9bdd230d451'	System	25 Jan 2021 17:10:24
User entered '0'	System	25 Jan 2021 17:10:24

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2021-01-25T12:08:23', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '32ac0bd8-f5fd-42a3-8d7e-a9bdd230d451'	System	25 Jan 2021 17:10:24
User entered '0'	System	25 Jan 2021 17:10:24

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2021-01-25T12:08:23', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '32ac0bd8-f5fd-42a3-8d7e-a9bdd230d451'	System	25 Jan 2021 17:10:24
User entered '0'	System	25 Jan 2021 17:10:24

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2021-01-25T12:08:23', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '32ac0bd8-f5fd-42a3-8d7e-a9bdd230d451'	System	25 Jan 2021 17:10:24
User entered '0'	System	25 Jan 2021 17:10:24

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2021-01-25T12:08:23', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '32ac0bd8-f5fd-42a3-8d7e-a9bdd230d451'	System	25 Jan 2021 17:10:24
User entered '0'	System	25 Jan 2021 17:10:24

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2021-01-25T12:08:23', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '32ac0bd8-f5fd-42a3-8d7e-a9bdd230d451'	System	25 Jan 2021 17:10:24
User entered '1'	System	25 Jan 2021 17:10:24

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2021-01-25T12:08:23', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '32ac0bd8-f5fd-42a3-8d7e-a9bdd230d451'	System	25 Jan 2021 17:10:24
User entered '0'	System	25 Jan 2021 17:10:24

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2021-01-25T12:08:23', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '32ac0bd8-f5fd-42a3-8d7e-a9bdd230d451'	System	25 Jan 2021 17:10:24
User entered '0'	System	25 Jan 2021 17:10:24

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2021-01-25T12:08:23', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '32ac0bd8-f5fd-42a3-8d7e-a9bdd230d451'	System	25 Jan 2021 17:10:24
User entered '0'	System	25 Jan 2021 17:10:24

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2021-01-25T12:08:23', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '32ac0bd8-f5fd-42a3-8d7e-a9bdd230d451'	System	25 Jan 2021 17:10:24
User entered '0'	System	25 Jan 2021 17:10:24

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2021-01-25T12:08:23', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '32ac0bd8-f5fd-42a3-8d7e-a9bdd230d451'	System	25 Jan 2021 17:10:24
User entered '0'	System	25 Jan 2021 17:10:24

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2021-01-25T12:08:40', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '32ac0bd8-f5fd-42a3-8d7e-a9bdd230d451'	System	25 Jan 2021 17:10:24
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	25 Jan 2021 17:10:24

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2021-01-25T12:08:56', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '32ac0bd8-f5fd-42a3-8d7e-a9bdd230d451'	System	25 Jan 2021 17:10:24
User entered 'No (N)'	System	25 Jan 2021 17:10:24

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2021-01-25T12:09:21', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '32ac0bd8-f5fd-42a3-8d7e-a9bdd230d451'	System	25 Jan 2021 17:10:24
User entered '25 Jan 2021 12:09:21'	System	25 Jan 2021 17:10:24

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '21 Jan 2021 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '25 Jan 2021 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '28 Jan 2021 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '01 Feb 2021 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[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 (3279c279ba745deb)', Time: '2021-02-04T21:16:12', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'e93e89be-0a74-4137-85bd-c1cd1fd5de7b'	System	05 Feb 2021 02:18:37
User entered 'No (N)'	System	05 Feb 2021 02:18:37

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

Have you been exposed to someone with 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 (3279c279ba745deb)', Time: '2021-02-04T21:16:18', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'e93e89be-0a74-4137-85bd-c1cd1fd5de7b'	System	05 Feb 2021 02:18:37
User entered 'No (N)'	System	05 Feb 2021 02:18:37

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2021-02-04T21:16:23', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'e93e89be-0a74-4137-85bd-c1cd1fd5de7b'	System	05 Feb 2021 02:18:37
User entered '04 Feb 2021 21:16:23'	System	05 Feb 2021 02:18:37

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '04 Feb 2021 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '08 Feb 2021 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[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 (3279c279ba745deb)', Time: '2021-02-13T16:24:05', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '321d9241-9ae1-4942-a8a9-da522baa4a53'	System	13 Feb 2021 21:24:56
User entered 'Yes (Y)'	System	13 Feb 2021 21:24:56

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

Have you been exposed to someone with 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 (3279c279ba745deb)', Time: '2021-02-13T16:24:10', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '321d9241-9ae1-4942-a8a9-da522baa4a53'	System	13 Feb 2021 21:24:56
User entered 'No (N)'	System	13 Feb 2021 21:24:56

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2021-02-13T16:24:14', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '321d9241-9ae1-4942-a8a9-da522baa4a53'	System	13 Feb 2021 21:24:56
User entered 'No (N)'	System	13 Feb 2021 21:24:56

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2021-02-13T16:24:39', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '321d9241-9ae1-4942-a8a9-da522baa4a53'	System	13 Feb 2021 21:24:56
User entered 'No (N)'	System	13 Feb 2021 21:24:56

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2021-02-13T16:24:54', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '321d9241-9ae1-4942-a8a9-da522baa4a53'	System	13 Feb 2021 21:24:56
User entered '13 Feb 2021 16:24:54'	System	13 Feb 2021 21:24:56

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '11 Feb 2021 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '15 Feb 2021 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[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 (3279c279ba745deb)', Time: '2021-02-22T12:09:48', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'e761dc29-4277-4aa0-b0e7-9d1cd54a8813'	System	22 Feb 2021 17:14:32
User entered 'No (N)'	System	22 Feb 2021 17:14:32

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

Have you been exposed to someone with 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 (3279c279ba745deb)', Time: '2021-02-22T12:09:52', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'e761dc29-4277-4aa0-b0e7-9d1cd54a8813'	System	22 Feb 2021 17:14:32
User entered 'No (N)'	System	22 Feb 2021 17:14:32

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2021-02-22T12:10:01', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'e761dc29-4277-4aa0-b0e7-9d1cd54a8813'	System	22 Feb 2021 17:14:32
User entered '22 Feb 2021 12:10:01'	System	22 Feb 2021 17:14:32

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '18 Feb 2021 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '22 Feb 2021 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[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 (3279c279ba745deb)', Time: '2021-02-27T11:29:13', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '0fc273dc-53d5-4139-bed3-f8cf842c125c'	System	27 Feb 2021 16:29:21
User entered 'No (N)'	System	27 Feb 2021 16:29:21

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

Have you been exposed to someone with 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 (3279c279ba745deb)', Time: '2021-02-27T11:29:16', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '0fc273dc-53d5-4139-bed3-f8cf842c125c'	System	27 Feb 2021 16:29:21
User entered 'No (N)'	System	27 Feb 2021 16:29:21

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2021-02-27T11:29:18', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '0fc273dc-53d5-4139-bed3-f8cf842c125c'	System	27 Feb 2021 16:29:21
User entered '27 Feb 2021 11:29:18'	System	27 Feb 2021 16:29:21

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '25 Feb 2021 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '01 Mar 2021 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[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 (3279c279ba745deb)', Time: '2021-03-08T11:42:13', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '19344e93-f2c6-452d-8c51-2c3397c1daf7'	System	08 Mar 2021 16:42:21
User entered 'No (N)'	System	08 Mar 2021 16:42:21

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

Have you been exposed to someone with 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 (3279c279ba745deb)', Time: '2021-03-08T11:42:16', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '19344e93-f2c6-452d-8c51-2c3397c1daf7'	System	08 Mar 2021 16:42:21
User entered 'No (N)'	System	08 Mar 2021 16:42:21

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2021-03-08T11:42:19', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '19344e93-f2c6-452d-8c51-2c3397c1daf7'	System	08 Mar 2021 16:42:21
User entered '08 Mar 2021 11:42:19'	System	08 Mar 2021 16:42:21

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '04 Mar 2021 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '08 Mar 2021 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[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 (3279c279ba745deb)', Time: '2021-03-11T15:00:14', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'f7319599-d62f-4b55-89b5-ba4303407992'	System	11 Mar 2021 20:00:25
User entered 'No (N)'	System	11 Mar 2021 20:00:25

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

Have you been exposed to someone with 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 (3279c279ba745deb)', Time: '2021-03-11T15:00:17', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'f7319599-d62f-4b55-89b5-ba4303407992'	System	11 Mar 2021 20:00:25
User entered 'No (N)'	System	11 Mar 2021 20:00:25

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2021-03-11T15:00:19', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'f7319599-d62f-4b55-89b5-ba4303407992'	System	11 Mar 2021 20:00:25
User entered '11 Mar 2021 15:00:19'	System	11 Mar 2021 20:00:25

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '11 Mar 2021 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '15 Mar 2021 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[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 (3279c279ba745deb)', Time: '2021-03-18T08:52:48', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '3e854f20-10bc-43fa-a5fd-3096f06f9f0e'	System	18 Mar 2021 12:53:23
User entered 'No (N)'	System	18 Mar 2021 12:53:23

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

Have you been exposed to someone with 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 (3279c279ba745deb)', Time: '2021-03-18T08:53:05', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '3e854f20-10bc-43fa-a5fd-3096f06f9f0e'	System	18 Mar 2021 12:53:23
User entered 'No (N)'	System	18 Mar 2021 12:53:23

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2021-03-18T08:53:20', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '3e854f20-10bc-43fa-a5fd-3096f06f9f0e'	System	18 Mar 2021 12:53:23
User entered '18 Mar 2021 08:53:20'	System	18 Mar 2021 12:53:23

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '18 Mar 2021 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '22 Mar 2021 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[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 (3279c279ba745deb)', Time: '2021-03-25T17:47:50', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'c4122ea1-ad5c-4a3e-b9ae-9438c7994618'	System	25 Mar 2021 21:48:06
User entered 'No (N)'	System	25 Mar 2021 21:48:06

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

Have you been exposed to someone with 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 (3279c279ba745deb)', Time: '2021-03-25T17:47:54', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'c4122ea1-ad5c-4a3e-b9ae-9438c7994618'	System	25 Mar 2021 21:48:06
User entered 'No (N)'	System	25 Mar 2021 21:48:06

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2021-03-25T17:48:01', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'c4122ea1-ad5c-4a3e-b9ae-9438c7994618'	System	25 Mar 2021 21:48:06
User entered '25 Mar 2021 17:48:01'	System	25 Mar 2021 21:48:06

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '25 Mar 2021 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '29 Mar 2021 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[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 (E1060AED-A99A-4434-A5F8-38473553D624)', Time: '2021-04-05T11:54:36-04:00', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '9a788c23-43c9-4815-b292-75acfe7da575'	System	05 Apr 2021 15:54:52
User entered 'No (N)'	System	05 Apr 2021 15:54:52

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

Have you been exposed to someone with 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 (E1060AED-A99A-4434-A5F8-38473553D624)', Time: '2021-04-05T11:54:40-04:00', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '9a788c23-43c9-4815-b292-75acfe7da575'	System	05 Apr 2021 15:54:52
User entered 'No (N)'	System	05 Apr 2021 15:54:52

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1060AED-A99A-4434-A5F8-38473553D624)', Time: '2021-04-05T11:54:43-04:00', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '9a788c23-43c9-4815-b292-75acfe7da575'	System	05 Apr 2021 15:54:52
User entered '05 Apr 2021 11:54:43'	System	05 Apr 2021 15:54:52

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '01 Apr 2021 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '05 Apr 2021 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[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 (E1060AED-A99A-4434-A5F8-38473553D624)', Time: '2021-04-08T08:07:38-04:00', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '052ec24d-b450-4d7a-854d-4881b9b0bf45'	System	08 Apr 2021 12:07:46
User entered 'No (N)'	System	08 Apr 2021 12:07:46

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

Have you been exposed to someone with 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 (E1060AED-A99A-4434-A5F8-38473553D624)', Time: '2021-04-08T08:07:41-04:00', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '052ec24d-b450-4d7a-854d-4881b9b0bf45'	System	08 Apr 2021 12:07:46
User entered 'No (N)'	System	08 Apr 2021 12:07:46

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1060AED-A99A-4434-A5F8-38473553D624)', Time: '2021-04-08T08:07:44-04:00', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '052ec24d-b450-4d7a-854d-4881b9b0bf45'	System	08 Apr 2021 12:07:46
User entered '08 Apr 2021 08:07:44'	System	08 Apr 2021 12:07:46

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '08 Apr 2021 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '12 Apr 2021 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[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 (E1060AED-A99A-4434-A5F8-38473553D624)', Time: '2021-04-16T08:55:32-04:00', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '41040c7d-2448-486e-843d-4b2122c60f0e'	System	16 Apr 2021 12:55:41
User entered 'No (N)'	System	16 Apr 2021 12:55:41

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

Have you been exposed to someone with 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 (E1060AED-A99A-4434-A5F8-38473553D624)', Time: '2021-04-16T08:55:35-04:00', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '41040c7d-2448-486e-843d-4b2122c60f0e'	System	16 Apr 2021 12:55:41
User entered 'No (N)'	System	16 Apr 2021 12:55:41

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1060AED-A99A-4434-A5F8-38473553D624)', Time: '2021-04-16T08:55:38-04:00', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '41040c7d-2448-486e-843d-4b2122c60f0e'	System	16 Apr 2021 12:55:41
User entered '16 Apr 2021 08:55:38'	System	16 Apr 2021 12:55:41

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '15 Apr 2021 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '19 Apr 2021 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[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 (E1060AED-A99A-4434-A5F8-38473553D624)', Time: '2021-04-22T07:34:29-04:00', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '472a39de-ffb1-41bf-8f41-e0dbff6084e5'	System	22 Apr 2021 11:34:39
User entered 'No (N)'	System	22 Apr 2021 11:34:39

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

Have you been exposed to someone with 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 (E1060AED-A99A-4434-A5F8-38473553D624)', Time: '2021-04-22T07:34:33-04:00', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '472a39de-ffb1-41bf-8f41-e0dbff6084e5'	System	22 Apr 2021 11:34:39
User entered 'No (N)'	System	22 Apr 2021 11:34:39

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1060AED-A99A-4434-A5F8-38473553D624)', Time: '2021-04-22T07:34:36-04:00', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: '472a39de-ffb1-41bf-8f41-e0dbff6084e5'	System	22 Apr 2021 11:34:39
User entered '22 Apr 2021 07:34:36'	System	22 Apr 2021 11:34:39

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '22 Apr 2021 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '26 Apr 2021 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[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 (E1060AED-A99A-4434-A5F8-38473553D624)', Time: '2021-04-29T08:29:00-04:00', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'bd91f375-760d-43c2-939a-d3031e22c245'	System	29 Apr 2021 12:29:16
User entered 'No (N)'	System	29 Apr 2021 12:29:16

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

Have you been exposed to someone with 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 (E1060AED-A99A-4434-A5F8-38473553D624)', Time: '2021-04-29T08:29:07-04:00', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'bd91f375-760d-43c2-939a-d3031e22c245'	System	29 Apr 2021 12:29:16
User entered 'No (N)'	System	29 Apr 2021 12:29:16

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1060AED-A99A-4434-A5F8-38473553D624)', Time: '2021-04-29T08:29:10-04:00', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'bd91f375-760d-43c2-939a-d3031e22c245'	System	29 Apr 2021 12:29:16
User entered '29 Apr 2021 08:29:10'	System	29 Apr 2021 12:29:16

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '29 Apr 2021 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '03 May 2021 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '06 May 2021 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '10 May 2021 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '13 May 2021 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '17 May 2021 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '20 May 2021 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '24 May 2021 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '27 May 2021 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '31 May 2021 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '03 Jun 2021 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '07 Jun 2021 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '10 Jun 2021 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '14 Jun 2021 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '17 Jun 2021 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '21 Jun 2021 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '24 Jun 2021 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '28 Jun 2021 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '01 Jul 2021 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '05 Jul 2021 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '08 Jul 2021 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '12 Jul 2021 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '15 Jul 2021 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '19 Jul 2021 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '22 Jul 2021 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '26 Jul 2021 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '29 Jul 2021 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '02 Aug 2021 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '05 Aug 2021 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '09 Aug 2021 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '12 Aug 2021 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '16 Aug 2021 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '19 Aug 2021 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '23 Aug 2021 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '26 Aug 2021 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '30 Aug 2021 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '02 Sep 2021 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '06 Sep 2021 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '09 Sep 2021 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '13 Sep 2021 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '16 Sep 2021 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '20 Sep 2021 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '23 Sep 2021 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '27 Sep 2021 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '30 Sep 2021 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '04 Oct 2021 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '07 Oct 2021 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '11 Oct 2021 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '14 Oct 2021 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '18 Oct 2021 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '21 Oct 2021 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '25 Oct 2021 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '28 Oct 2021 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '01 Nov 2021 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '04 Nov 2021 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '08 Nov 2021 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '11 Nov 2021 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '15 Nov 2021 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '18 Nov 2021 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '22 Nov 2021 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '25 Nov 2021 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '29 Nov 2021 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '02 Dec 2021 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '06 Dec 2021 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '09 Dec 2021 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '13 Dec 2021 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '16 Dec 2021 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '20 Dec 2021 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '23 Dec 2021 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '27 Dec 2021 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '30 Dec 2021 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '03 Jan 2022 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '06 Jan 2022 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '10 Jan 2022 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '13 Jan 2022 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '17 Jan 2022 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '20 Jan 2022 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '24 Jan 2022 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '27 Jan 2022 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '31 Jan 2022 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '03 Feb 2022 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '07 Feb 2022 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '10 Feb 2022 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '14 Feb 2022 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '17 Feb 2022 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '21 Feb 2022 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '24 Feb 2022 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '28 Feb 2022 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '03 Mar 2022 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '07 Mar 2022 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '10 Mar 2022 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '14 Mar 2022 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '17 Mar 2022 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '21 Mar 2022 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '24 Mar 2022 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '28 Mar 2022 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '31 Mar 2022 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '04 Apr 2022 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '07 Apr 2022 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '11 Apr 2022 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '14 Apr 2022 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '18 Apr 2022 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '21 Apr 2022 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '25 Apr 2022 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '28 Apr 2022 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '02 May 2022 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '05 May 2022 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '09 May 2022 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '12 May 2022 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '16 May 2022 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '19 May 2022 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '23 May 2022 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '26 May 2022 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '30 May 2022 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '02 Jun 2022 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '06 Jun 2022 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '09 Jun 2022 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '13 Jun 2022 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '16 Jun 2022 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '20 Jun 2022 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '23 Jun 2022 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '27 Jun 2022 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '30 Jun 2022 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '04 Jul 2022 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '07 Jul 2022 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '11 Jul 2022 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '14 Jul 2022 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '18 Jul 2022 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '21 Jul 2022 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '25 Jul 2022 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '28 Jul 2022 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '01 Aug 2022 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '04 Aug 2022 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '08 Aug 2022 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '11 Aug 2022 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '15 Aug 2022 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '18 Aug 2022 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '22 Aug 2022 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '25 Aug 2022 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '29 Aug 2022 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '01 Sep 2022 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '05 Sep 2022 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '08 Sep 2022 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '12 Sep 2022 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '15 Sep 2022 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '19 Sep 2022 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '22 Sep 2022 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '26 Sep 2022 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '29 Sep 2022 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '03 Oct 2022 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '06 Oct 2022 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '10 Oct 2022 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '13 Oct 2022 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '17 Oct 2022 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '20 Oct 2022 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '24 Oct 2022 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '27 Oct 2022 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '31 Oct 2022 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '03 Nov 2022 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '07 Nov 2022 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '10 Nov 2022 00:01'	System	20 Nov 2020 06:04:36

US3472020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:36
Amendment Manager: User entered '14 Nov 2022 23:59'	System	20 Nov 2020 06:04:36

US3472020

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:45:01

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 12:46:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2021-03-08T11:42:26', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'c226e7d0-a052-4c1c-bcb5-f3e484b5aef1'	System	08 Mar 2021 16:42:34
User entered 'No (N)'	System	08 Mar 2021 16:42:34

US3472020

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:45:01

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:46:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3279c279ba745deb)', Time: '2021-03-08T11:42:30', User OID: 'PatientReportedOutcome (US3472020)', ODM File OID: 'c226e7d0-a052-4c1c-bcb5-f3e484b5aef1'	System	08 Mar 2021 16:42:34
User entered '08 Mar 2021 11:42:30'	System	08 Mar 2021 16:42:34

US3472020

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:16:26
User entered 'Yes (Y)'		30 Nov 2020 16:43:48

US3472020

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:01

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:16:26
User entered '30 Nov 2020'		30 Nov 2020 16:43:48

US3472020

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:16:26
User entered 'Contact Made (CONTACT MADE)'		30 Nov 2020 16:43:48

US3472020

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:16:26
User entered empty.		30 Nov 2020 16:43:48

US3472020

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:16:31
User entered 'Yes (Y)'		30 Nov 2020 16:43:53

US3472020

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:01:14
User entered '1'	System	30 Nov 2020 16:43:53

US3472020

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:49:37
DataPoint Verified.		08 Apr 2021 15:51:15
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Jan 2021 15:49:34

US3472020

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:49:37
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:15
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered '02 Jan 2021'	(b) (4) (b) (4), (b) (6)	02 Jan 2021 15:49:34

US3472020

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:49:37
DataPoint Verified.	[REDACTED]	08 Apr 2021 15:51:15
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Jan 2021 15:49:34

US3472020

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:49:37
DataPoint Verified.	(b) (4)	08 Apr 2021 15:51:15
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Jan 2021 15:49:34

US3472020

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:49:37
DataPoint Verified.		08 Apr 2021 15:51:15
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Jan 2021 15:49:38

US3472020

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:49:37
User entered '1'	System	02 Jan 2021 15:49:38

US3472020

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:49:37
DataPoint Verified.	[REDACTED]	08 Apr 2021 15:51:15
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6) [REDACTED]	03 Feb 2021 20:05:08

US3472020

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:49:37
DataPoint Verified.	[REDACTED]	08 Apr 2021 15:51:15
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered '03 Feb 2021'	(b) (4) (b) (4), (b) (6) [REDACTED]	03 Feb 2021 20:05:08

US3472020

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:49:37
DataPoint Verified.		08 Apr 2021 15:51:15
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 20:05:08

US3472020

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:49:37
DataPoint Verified.	(b) (4)	08 Apr 2021 15:51:15
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 20:05:08

US3472020

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:49:37
DataPoint Verified.	[REDACTED]	08 Apr 2021 15:51:15
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 20:05:14

US3472020

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:49:37
User entered '1'	System	03 Feb 2021 20:05:14

US3472020

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:49:37
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:15
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 00:56:53

US3472020

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:49:37
DataPoint Verified.	[REDACTED]	08 Apr 2021 15:51:15
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered '3 Mar 2021'	(b) (4) (b) (4), (b) (6) [REDACTED]	04 Mar 2021 00:56:53

US3472020

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:49:37
DataPoint Verified.	(b) (4)	08 Apr 2021 15:51:15
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 00:56:53

US3472020

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:49:37
DataPoint Verified.	(b) (4)	08 Apr 2021 15:51:15
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 00:56:53

US3472020

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:49:37
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:15
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 00:56:58

US3472020

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:49:37
User entered '1'	System	04 Mar 2021 00:56:58

US3472020

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:45:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:26
DataPoint Verified.	(b) (4)	08 Apr 2021 16:12:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Apr 2021 16:38:39

US3472020

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:26
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:12:06
User entered '05 Apr 2021'		06 Apr 2021 16:38:39

US3472020

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:45:01

[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 18:58:26
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:12:06
User entered 'Clinic (Clinic)'		06 Apr 2021 16:38:39

US3472020

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:45:01

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	06 Apr 2021 16:38:39

US3472020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:12:06
User entered 'Yes (Y)'		06 Apr 2021 16:40:47

US3472020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:26
DataPoint Verified.	(b) (4)	08 Apr 2021 16:12:06
User entered '05 Apr 2021'	(b) (4), (b) (6)	06 Apr 2021 16:40:47

US3472020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:12:06
User entered '11:43'		06 Apr 2021 16:40:47

US3472020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
User entered '05 Apr 2021 11:43'	System	06 Apr 2021 16:40:47

US3472020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:26
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:12:06
User entered '97.7' F	(b) (4)	06 Apr 2021 16:40:47

US3472020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:26
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:12:06
User entered 'Oral (Oral)'		06 Apr 2021 16:40:47

US3472020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:26
DataPoint Verified.	(b) (4)	08 Apr 2021 16:12:06
User entered empty.	(b) (4), (b) (6)	06 Apr 2021 16:40:47

US3472020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:26
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:12:06
User entered '78'		06 Apr 2021 16:40:47

US3472020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	06 Apr 2021 16:40:47

US3472020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:26
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:12:06
User entered '16'	(b) (4), (b) (6)	06 Apr 2021 16:40:47

US3472020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	06 Apr 2021 16:40:47

US3472020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:12:06
User entered '128'		06 Apr 2021 16:40:47

US3472020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	06 Apr 2021 16:40:47

US3472020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:26
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:12:06
User entered '77'	(b) (4)	06 Apr 2021 16:40:47

US3472020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	06 Apr 2021 16:40:47

US3472020

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:45:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:26
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:12:06
User entered 'No (N)'	(b) (4)	06 Apr 2021 16:40:53

US3472020

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:45:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:26
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:12:06
User entered empty.	(b) (4)	06 Apr 2021 16:40:53

US3472020

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:45:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:12:06
User entered 'Yes (Y)'		06 Apr 2021 16:41:07

US3472020

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:45:01

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:26
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:12:06
User entered '05 Apr 2021'	(b) (4)	06 Apr 2021 16:41:07

US3472020

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:45:01

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:26
DataPoint Verified.	(b) (4)	08 Apr 2021 16:12:06
User entered '11:45'	(b) (4), (b) (6)	06 Apr 2021 16:41:07

US3472020

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
User entered '05 Apr 2021 11:45'	System	06 Apr 2021 16:41:07

US3472020

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4)	08 Apr 2021 16:12:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Apr 2021 16:41:12

US3472020

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Apr 2021 16:41:12

US3472020

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 May 2021 17:33:15

US3472020

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
User entered '2 May 2021'	(b) (4) (b) (4), (b) (6)	02 May 2021 17:33:15

US3472020

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 May 2021 17:33:15

US3472020

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
User entered empty.	(b) (4) (b) (4), (b) (6)	02 May 2021 17:33:15

US3472020

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 May 2021 17:33:20

US3472020

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	02 May 2021 17:33:20

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:45:01

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:02
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User closed query 'Per CDM: It appears initial start date of symptoms and Contact Date are the same (03DEC2020). Please review and reconcile' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Jan 2021 09:52:24
Query 'Per CDM: It appears initial start date of symptoms and Contact Date are the same (03DEC2020). Please review and reconcile' answered with 'dates are the same - data entered correctly' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 14:17:27
User opened query 'Per CDM: It appears initial start date of symptoms and Contact Date are the same (03DEC2020). Please review and reconcile' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 19:41:54
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:18:54
User entered '03 Dec 2020'	(b) (4), (b) (6)	06 Dec 2020 22:43:17

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:45:01

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:02
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:18:54
User entered '16:45'		06 Dec 2020 22:43:17

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:45:01

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:02
User entered '03 Dec 2020 16:45'	System	06 Dec 2020 22:43:17

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:45:01

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:02
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:18:54
User entered 'Safety Call (Safety Call)'		06 Dec 2020 22:43:17

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:45:01

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:02
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:18:54
User entered 'Yes (Y)'		06 Dec 2020 22:43:17

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:45:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered 'Day 1 (Day 1)'	(b) (4) (b) (4), (b) (6)	06 Dec 2020 22:43:28

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:45:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered '03 Dec 2020'	(b) (4), (b) (6)	06 Dec 2020 22:43:28

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:45:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Dec 2020 22:50:17
User entered '1'	(b) (4), (b) (6)	06 Dec 2020 22:43:28

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:45:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	06 Dec 2020 22:50:17
User entered empty.	(b) (4), (b) (6)	06 Dec 2020 22:43:28

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:45:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User entered '%'	System	06 Dec 2020 22:50:17
User entered empty.	System	06 Dec 2020 22:43:28

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:45:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	06 Dec 2020 22:50:17
User entered empty.	(b) (4), (b) (6)	06 Dec 2020 22:43:28

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:45:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Dec 2020 22:50:17
User entered empty.	(b) (4), (b) (6)	06 Dec 2020 22:43:28

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:45:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Dec 2020 22:50:17
User entered empty.	(b) (4), (b) (6)	06 Dec 2020 22:43:28

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:45:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)' reason for change: Data Entry Error		06 Dec 2020 22:50:17
User entered empty.		06 Dec 2020 22:43:28

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:45:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)' reason for change: Data Entry Error		06 Dec 2020 22:50:17
User entered empty.		06 Dec 2020 22:43:28

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:45:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)' reason for change: Data Entry Error		06 Dec 2020 22:50:17
User entered empty.		06 Dec 2020 22:43:28

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:45:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)' reason for change: Data Entry Error		06 Dec 2020 22:50:17
User entered empty.		06 Dec 2020 22:43:28

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:45:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)' reason for change: Data Entry Error		06 Dec 2020 22:50:17
User entered empty.		06 Dec 2020 22:43:28

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:45:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)' reason for change: Data Entry Error		06 Dec 2020 22:50:17
User entered empty.		06 Dec 2020 22:43:28

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:45:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	06 Dec 2020 22:50:17
User entered empty.	(b) (4)	06 Dec 2020 22:43:28

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:45:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)' reason for change: Data Entry Error		06 Dec 2020 22:50:17
User entered empty.		06 Dec 2020 22:43:28

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:45:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)' reason for change: Data Entry Error		06 Dec 2020 22:50:17
User entered empty.		06 Dec 2020 22:43:28

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:45:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)' reason for change: Data Entry Error		06 Dec 2020 22:50:17
User entered empty.		06 Dec 2020 22:43:28

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:45:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)' reason for change: Data Entry Error		06 Dec 2020 22:50:17
User entered empty.		06 Dec 2020 22:43:28

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:45:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)' reason for change: Data Entry Error		06 Dec 2020 22:50:17
User entered empty.		06 Dec 2020 22:43:28

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:45:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)' reason for change: Data Entry Error		06 Dec 2020 22:50:17
User entered empty.		06 Dec 2020 22:43:28

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:45:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)' reason for change: Data Entry Error		06 Dec 2020 22:50:17
User entered empty.		06 Dec 2020 22:43:28

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:45:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered 'Day 2 (Day 2)'	(b) (4) (b) (4), (b) (6)	06 Dec 2020 22:50:17

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:45:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered '04 Dec 2020'		06 Dec 2020 22:50:17

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:45:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered '0'		06 Dec 2020 22:50:17

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:45:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered '95'		06 Dec 2020 22:50:17

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:45:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User entered '%'	System	06 Dec 2020 22:50:17

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:45:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered '99.8' F		06 Dec 2020 22:50:17

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:45:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		06 Dec 2020 22:50:17

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:45:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)'		06 Dec 2020 22:50:17

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:45:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)'		06 Dec 2020 22:50:17

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:45:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		06 Dec 2020 22:50:17

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:45:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)'		06 Dec 2020 22:50:17

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:45:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)'	(b) (4), (b) (6)	06 Dec 2020 22:50:17

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:45:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)'		06 Dec 2020 22:50:17

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:45:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		06 Dec 2020 22:50:17

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:45:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		06 Dec 2020 22:50:17

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:45:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'	(b) (4), (b) (6)	06 Dec 2020 22:50:17

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:45:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		06 Dec 2020 22:50:17

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:45:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		06 Dec 2020 22:50:17

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:45:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4)	24 Dec 2020 04:23:08
User entered 'None (None)'	(b) (4), (b) (6)	06 Dec 2020 22:50:17

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:45:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4)	24 Dec 2020 04:23:08
User entered 'None (None)'	(b) (4), (b) (6)	06 Dec 2020 22:50:17

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:45:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		06 Dec 2020 22:50:17

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:45:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		06 Dec 2020 22:50:17

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:45:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered 'Day 3 (Day 3)'	(b) (4) (b) (4), (b) (6)	06 Dec 2020 22:52:49

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:45:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered '05 Dec 2020'		06 Dec 2020 22:52:49

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:45:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered '0'		06 Dec 2020 22:52:49

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:45:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered '97'		06 Dec 2020 22:52:49

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:45:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User entered '%'	System	06 Dec 2020 22:52:49

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:45:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered '97.0' F		06 Dec 2020 22:52:49

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:45:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		06 Dec 2020 22:52:49

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:45:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)'		06 Dec 2020 22:52:49

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:45:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)'		06 Dec 2020 22:52:49

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:45:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		06 Dec 2020 22:52:49

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:45:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Moderate (Moderate)'		06 Dec 2020 22:52:49

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:45:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)'		06 Dec 2020 22:52:49

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:45:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)'		06 Dec 2020 22:52:49

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:45:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		06 Dec 2020 22:52:49

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:45:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	06 Dec 2020 22:52:49

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:45:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	06 Dec 2020 22:52:49

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:45:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		06 Dec 2020 22:52:49

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:45:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		06 Dec 2020 22:52:49

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:45:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		06 Dec 2020 22:52:49

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:45:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'	(b) (4), (b) (6)	06 Dec 2020 22:52:49

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:45:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		06 Dec 2020 22:52:49

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:45:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		06 Dec 2020 22:52:49

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:45:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered 'Day 4 (Day 4)'	(b) (4) (b) (4), (b) (6)	06 Dec 2020 22:58:01

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:45:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	06 Dec 2020 22:58:06
User entered '06 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Dec 2020 22:58:06
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	06 Dec 2020 22:58:01
User entered '-6 Dec 2020' (non-conformant).	(b) (4), (b) (6)	06 Dec 2020 22:58:01

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:45:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered '0'		06 Dec 2020 22:58:01

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:45:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered '98'		06 Dec 2020 22:58:01

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:45:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User entered '%'	System	06 Dec 2020 22:58:01

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:45:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered '98.0' F		06 Dec 2020 22:58:01

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:45:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		06 Dec 2020 22:58:01

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:45:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)'		06 Dec 2020 22:58:01

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:45:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)'		06 Dec 2020 22:58:01

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:45:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		06 Dec 2020 22:58:01

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:45:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Moderate (Moderate)'		06 Dec 2020 22:58:01

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:45:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)'		06 Dec 2020 22:58:01

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:45:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)'		06 Dec 2020 22:58:01

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:45:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		06 Dec 2020 22:58:01

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:45:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	06 Dec 2020 22:58:01

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:45:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	06 Dec 2020 22:58:01

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:45:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		06 Dec 2020 22:58:01

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:45:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		06 Dec 2020 22:58:01

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:45:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		06 Dec 2020 22:58:01

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:45:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		06 Dec 2020 22:58:01

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:45:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		06 Dec 2020 22:58:01

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:45:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		06 Dec 2020 22:58:01

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:45:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered 'Day 5 (Day 5)'	(b) (4) (b) (4), (b) (6)	08 Dec 2020 15:12:18

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:45:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	08 Dec 2020 15:12:23
User entered '07 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Dec 2020 15:12:23
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	08 Dec 2020 15:12:18
User entered '-7 Dec 2020' (non-conformant).	(b) (4), (b) (6)	08 Dec 2020 15:12:18

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:45:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered '0'		08 Dec 2020 15:12:18

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:45:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered '98'		08 Dec 2020 15:12:18

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:45:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User entered '%'	System	08 Dec 2020 15:12:18

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:45:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered '98.3' F		08 Dec 2020 15:12:18

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:45:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		08 Dec 2020 15:12:18

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:45:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)'		08 Dec 2020 15:12:18

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:45:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)'		08 Dec 2020 15:12:18

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:45:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		08 Dec 2020 15:12:18

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:45:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Moderate (Moderate)'		08 Dec 2020 15:12:18

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:45:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)'		08 Dec 2020 15:12:18

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:45:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)'		08 Dec 2020 15:12:18

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:45:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		08 Dec 2020 15:12:18

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:45:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Moderate (Moderate)'		08 Dec 2020 15:12:18

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:45:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Moderate (Moderate)'		08 Dec 2020 15:12:18

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:45:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		08 Dec 2020 15:12:18

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:45:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		08 Dec 2020 15:12:18

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:45:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		08 Dec 2020 15:12:18

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:45:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		08 Dec 2020 15:12:18

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:45:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		08 Dec 2020 15:12:18

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:45:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		08 Dec 2020 15:12:18

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:45:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered 'Day 6 (Day 6)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:06:53

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:45:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered '08 Dec 2020'		09 Dec 2020 21:06:53

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:45:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered '0'		09 Dec 2020 21:06:53

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:45:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered '99'		09 Dec 2020 21:06:53

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:45:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User entered '%'	System	09 Dec 2020 21:06:53

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:45:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered '98.0' F		09 Dec 2020 21:06:53

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:45:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		09 Dec 2020 21:06:53

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:45:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)'		09 Dec 2020 21:06:53

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:45:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)'		09 Dec 2020 21:06:53

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:45:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		09 Dec 2020 21:06:53

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:45:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)'		09 Dec 2020 21:06:53

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:45:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)'		09 Dec 2020 21:06:53

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:45:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)'		09 Dec 2020 21:06:53

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:45:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		09 Dec 2020 21:06:53

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:45:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Moderate (Moderate)'		09 Dec 2020 21:06:53

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:45:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	09 Dec 2020 21:06:53

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:45:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		09 Dec 2020 21:06:53

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:45:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		09 Dec 2020 21:06:53

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:45:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		09 Dec 2020 21:06:53

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:45:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		09 Dec 2020 21:06:53

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:45:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		09 Dec 2020 21:06:53

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:45:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		09 Dec 2020 21:06:53

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:45:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered 'Day 7 (Day 7)'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:11:20

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:45:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered '09 Dec 2020'	(b) (4), (b) (6)	10 Dec 2020 19:11:20

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:45:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered '0'		10 Dec 2020 19:11:20

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:45:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered '98'		10 Dec 2020 19:11:20

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:45:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User entered '%'	System	10 Dec 2020 19:11:20

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:45:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered '98.3' F		10 Dec 2020 19:11:20

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:45:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		10 Dec 2020 19:11:20

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:45:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)'		10 Dec 2020 19:11:20

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:45:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'	(b) (4), (b) (6)	10 Dec 2020 19:11:20

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:45:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		10 Dec 2020 19:11:20

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:45:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)'		10 Dec 2020 19:11:20

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:45:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		10 Dec 2020 19:11:20

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:45:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		10 Dec 2020 19:11:20

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:45:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		10 Dec 2020 19:11:20

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:45:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Moderate (Moderate)'		10 Dec 2020 19:11:20

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:45:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)'		10 Dec 2020 19:11:20

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:45:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)'		10 Dec 2020 19:11:20

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:45:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		10 Dec 2020 19:11:20

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:45:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		10 Dec 2020 19:11:20

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:45:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		10 Dec 2020 19:11:20

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:45:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		10 Dec 2020 19:11:20

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:45:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		10 Dec 2020 19:11:20

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:45:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered 'Day 8 (Day 8)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 19:42:34

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:45:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered '10 Dec 2020'		14 Dec 2020 19:42:34

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:45:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered '0'		14 Dec 2020 19:42:34

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:45:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered '99' reason for change: Data Entry Error	(b) (4)	14 Dec 2020 19:50:03
User entered '95'	(b) (4)	14 Dec 2020 19:42:34

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:45:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User entered '%'	System	14 Dec 2020 19:42:34

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:45:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered '97.6' F reason for change: Data Entry Error	(b) (4)	14 Dec 2020 19:50:03
User entered '99.1' F	(b) (4)	14 Dec 2020 19:42:34

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:45:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)' reason for change: Data Entry Error		14 Dec 2020 19:50:03
User entered 'Mild (Mild)'		14 Dec 2020 19:42:34

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:45:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)'		14 Dec 2020 19:42:34

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:45:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		14 Dec 2020 19:42:34

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:45:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		14 Dec 2020 19:42:34

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:45:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	14 Dec 2020 19:42:34

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:45:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)'		14 Dec 2020 19:42:34

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:45:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)'		14 Dec 2020 19:42:34

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:45:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		14 Dec 2020 19:42:34

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:45:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)'		14 Dec 2020 19:42:34

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:45:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Moderate (Moderate)' reason for change: Data Entry Error		14 Dec 2020 19:50:03
User entered 'Mild (Mild)'		14 Dec 2020 19:42:34

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:45:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		14 Dec 2020 19:42:34

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:45:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		14 Dec 2020 19:42:34

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:45:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		14 Dec 2020 19:42:34

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:45:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		14 Dec 2020 19:42:34

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:45:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		14 Dec 2020 19:42:34

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:45:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		14 Dec 2020 19:42:34

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:45:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered 'Day 9 (Day 9)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 19:46:44

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:45:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered '11 Dec 2020'		14 Dec 2020 19:46:44

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:45:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered '0'		14 Dec 2020 19:46:44

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:45:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered '95' reason for change: Data Entry Error		14 Dec 2020 19:50:03
User entered '98'		14 Dec 2020 19:46:44

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:45:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User entered '%'	System	14 Dec 2020 19:46:44

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:45:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered '99.1' F reason for change: Data Entry Error		14 Dec 2020 19:50:03
User entered '98.0' F		14 Dec 2020 19:46:44

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:45:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)'	(b) (4), (b) (6)	14 Dec 2020 19:46:44

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:45:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)'		14 Dec 2020 19:46:44

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:45:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		14 Dec 2020 19:46:44

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:45:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		14 Dec 2020 19:46:44

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:45:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Moderate (Moderate)'		14 Dec 2020 19:46:44

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:45:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)'	(b) (4), (b) (6)	14 Dec 2020 19:46:44

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:45:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)'		14 Dec 2020 19:46:44

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:45:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		14 Dec 2020 19:46:44

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:45:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)'		14 Dec 2020 19:46:44

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:45:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)'		14 Dec 2020 19:46:44

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:45:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		14 Dec 2020 19:46:44

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:45:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	4 Dec 2020 04:23:08
User entered 'None (None)'	(b) (4), (b) (6)	4 Dec 2020 19:46:44

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:45:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		14 Dec 2020 19:46:44

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:45:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		14 Dec 2020 19:46:44

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:45:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		14 Dec 2020 19:46:44

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:45:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		14 Dec 2020 19:46:44

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:45:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered 'Day 10 (Day 10)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 19:50:03

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:45:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered '12 Dec 2020'		14 Dec 2020 19:50:03

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:45:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered '0'		14 Dec 2020 19:50:03

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:45:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered '98'		14 Dec 2020 19:50:03

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:45:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User entered '%'	System	14 Dec 2020 19:50:03

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:45:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered '98.0' F		14 Dec 2020 19:50:03

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:45:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)'		14 Dec 2020 19:50:03

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:45:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)'		14 Dec 2020 19:50:03

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:45:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		14 Dec 2020 19:50:03

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:45:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		14 Dec 2020 19:50:03

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:45:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Moderate (Moderate)'		14 Dec 2020 19:50:03

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:45:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)'	(b) (4), (b) (6)	14 Dec 2020 19:50:03

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:45:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)'		14 Dec 2020 19:50:03

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:45:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		14 Dec 2020 19:50:03

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:45:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		14 Dec 2020 19:50:03

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:45:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)'		14 Dec 2020 19:50:03

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:45:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)'	(b) (4), (b) (6)	14 Dec 2020 19:50:03

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:45:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		14 Dec 2020 19:50:03

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:45:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		14 Dec 2020 19:50:03

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:45:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		14 Dec 2020 19:50:03

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:45:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		14 Dec 2020 19:50:03

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:45:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		14 Dec 2020 19:50:03

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:45:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered 'Day 11 (Day 11)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 19:59:25

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:45:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered '13 Dec 2020'		14 Dec 2020 19:59:25

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:45:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered '0'		14 Dec 2020 19:59:25

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:45:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered '99'		14 Dec 2020 19:59:25

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:45:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User entered '%'	System	14 Dec 2020 19:59:25

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:45:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered '98.0' F		14 Dec 2020 19:59:25

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:45:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		14 Dec 2020 19:59:25

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:45:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)'	(b) (4), (b) (6)	14 Dec 2020 19:59:25

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:45:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		14 Dec 2020 19:59:25

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:45:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		14 Dec 2020 19:59:25

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:45:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)'		14 Dec 2020 19:59:25

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:45:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		14 Dec 2020 19:59:25

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:45:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		14 Dec 2020 19:59:25

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:45:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		14 Dec 2020 19:59:25

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:45:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)'		14 Dec 2020 19:59:25

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:45:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)'		14 Dec 2020 19:59:25

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:45:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		14 Dec 2020 19:59:25

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:45:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 19:59:25

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:45:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		14 Dec 2020 19:59:25

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:45:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		14 Dec 2020 19:59:25

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:45:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		14 Dec 2020 19:59:25

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:45:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 19:59:25

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:45:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered 'Day 12 (Day 12)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 20:17:48

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:45:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered '14 Dec 2020'	(b) (4), (b) (6)	17 Dec 2020 20:17:48

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:45:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered '0'		17 Dec 2020 20:17:48

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:45:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered '99'		17 Dec 2020 20:17:48

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:45:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User entered '%'	System	17 Dec 2020 20:17:48

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:45:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered '97.0' F		17 Dec 2020 20:17:48

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:45:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		17 Dec 2020 20:17:48

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:45:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)'		17 Dec 2020 20:17:48

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:45:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		17 Dec 2020 20:17:48

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:45:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'	(b) (4), (b) (6)	17 Dec 2020 20:17:48

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:45:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)'		17 Dec 2020 20:17:48

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:45:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'	(b) (4), (b) (6)	17 Dec 2020 20:17:48

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:45:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		17 Dec 2020 20:17:48

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:45:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		17 Dec 2020 20:17:48

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:45:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)'	(b) (4), (b) (6)	17 Dec 2020 20:17:48

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:45:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)'		17 Dec 2020 20:17:48

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:45:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		17 Dec 2020 20:17:48

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:45:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		17 Dec 2020 20:17:48

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:45:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		17 Dec 2020 20:17:48

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:45:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		17 Dec 2020 20:17:48

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:45:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		17 Dec 2020 20:17:48

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:45:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'	(b) (4), (b) (6)	17 Dec 2020 20:17:48

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:45:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered 'Day 13 (Day 13)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 20:21:44

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:45:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered '15 Dec 2020'		17 Dec 2020 20:21:44

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:45:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered '0'		17 Dec 2020 20:21:44

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:45:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered '99'		17 Dec 2020 20:21:44

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:45:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User entered '%'	System	17 Dec 2020 20:21:44

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:45:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered '97.2' F reason for change: Data Entry Error		17 Dec 2020 20:22:59
User entered '97.2' C		17 Dec 2020 20:21:44

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:45:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		17 Dec 2020 20:21:44

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:45:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)'		17 Dec 2020 20:21:44

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:45:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		17 Dec 2020 20:21:44

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:45:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		17 Dec 2020 20:21:44

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:45:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)'		17 Dec 2020 20:21:44

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:45:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		17 Dec 2020 20:21:44

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:45:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		17 Dec 2020 20:21:44

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:45:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		17 Dec 2020 20:21:44

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:45:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)'		17 Dec 2020 20:21:44

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:45:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)'	(b) (4), (b) (6)	17 Dec 2020 20:21:44

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:45:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		17 Dec 2020 20:21:44

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:45:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		17 Dec 2020 20:21:44

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:45:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		17 Dec 2020 20:21:44

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:45:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		17 Dec 2020 20:21:44

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:45:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		17 Dec 2020 20:21:44

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:45:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		17 Dec 2020 20:21:44

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:45:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered 'Day 14 (Day 14)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 20:22:59

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:45:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered '16 Dec 2020'		17 Dec 2020 20:22:59

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:45:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered '0'		17 Dec 2020 20:22:59

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:45:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered '99'		17 Dec 2020 20:22:59

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:45:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User entered '%'	System	17 Dec 2020 20:22:59

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:45:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered '97.1' F		17 Dec 2020 20:22:59

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:45:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		17 Dec 2020 20:22:59

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:45:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)'		17 Dec 2020 20:22:59

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:45:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		17 Dec 2020 20:22:59

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:45:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		17 Dec 2020 20:22:59

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:45:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)'	(b) (4), (b) (6)	17 Dec 2020 20:22:59

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:45:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		17 Dec 2020 20:22:59

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:45:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		17 Dec 2020 20:22:59

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:45:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)'		17 Dec 2020 20:22:59

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:45:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)'	(b) (4), (b) (6)	17 Dec 2020 20:22:59

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:45:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)'		17 Dec 2020 20:22:59

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:45:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		17 Dec 2020 20:22:59

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:45:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4)	24 Dec 2020 04:23:08
User entered 'None (None)'	(b) (4), (b) (6)	17 Dec 2020 20:22:59

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:45:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		17 Dec 2020 20:22:59

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:45:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'	(b) (4), (b) (6)	17 Dec 2020 20:22:59

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:45:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		17 Dec 2020 20:22:59

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:45:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		17 Dec 2020 20:22:59

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:45:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered 'Day 15 (Day 15)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:22:11

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:45:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered '17 Dec 2020'		21 Dec 2020 20:22:11

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:45:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered '0'		21 Dec 2020 20:22:11

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:45:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered '98' reason for change: Data Entry Error		21 Dec 2020 20:23:25
User entered '97'		21 Dec 2020 20:22:11

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:45:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User entered '%'	System	21 Dec 2020 20:22:11

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:45:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered '97.6' F reason for change: Data Entry Error		21 Dec 2020 20:23:25
User entered '98.0' F		21 Dec 2020 20:22:11

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:45:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		21 Dec 2020 20:22:11

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:45:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'Mild (Mild)'		21 Dec 2020 20:22:11

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:45:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'	(b) (4), (b) (6)	21 Dec 2020 20:22:11

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:45:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		21 Dec 2020 20:22:11

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:45:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		21 Dec 2020 20:22:11

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:45:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'	(b) (4), (b) (6)	21 Dec 2020 20:22:11

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:45:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'	(b) (4), (b) (6)	21 Dec 2020 20:22:11

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:45:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		21 Dec 2020 20:22:11

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:45:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		21 Dec 2020 20:22:11

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:45:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		21 Dec 2020 20:22:11

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:45:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		21 Dec 2020 20:22:11

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:45:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		21 Dec 2020 20:22:11

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:45:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		21 Dec 2020 20:22:11

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:45:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		21 Dec 2020 20:22:11

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:45:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'	(b) (4), (b) (6)	21 Dec 2020 20:22:11

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:45:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		21 Dec 2020 20:22:11

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:45:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered 'Day 16 (Day 16)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:22:11

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:45:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered '18 Dec 2020'	(b) (4), (b) (6)	21 Dec 2020 20:22:11

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:45:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered '0'		21 Dec 2020 20:22:11

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:45:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered '97'		21 Dec 2020 20:22:11

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:45:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User entered '%'	System	21 Dec 2020 20:22:11

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:45:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered '98.0' F		21 Dec 2020 20:22:11

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:45:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		21 Dec 2020 20:22:11

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:45:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		21 Dec 2020 20:22:11

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:45:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		21 Dec 2020 20:22:11

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:45:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'	(b) (4), (b) (6)	21 Dec 2020 20:22:11

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:45:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		21 Dec 2020 20:22:11

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:45:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		21 Dec 2020 20:22:11

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:45:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		21 Dec 2020 20:22:11

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:45:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		21 Dec 2020 20:22:11

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:45:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		21 Dec 2020 20:22:11

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:45:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'	(b) (4), (b) (6)	21 Dec 2020 20:22:11

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:45:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		21 Dec 2020 20:22:11

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:45:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		21 Dec 2020 20:22:11

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:45:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		21 Dec 2020 20:22:11

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:45:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		21 Dec 2020 20:22:11

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:45:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		21 Dec 2020 20:22:11

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:45:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:08
User entered 'None (None)'		21 Dec 2020 20:22:11

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:45:01

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:10
DataPoint Verified.	(b) (4)	08 Apr 2021 15:51:15
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered '04 Dec 2020'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:09:31

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:45:01

[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 22:06:10
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:15
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:09:31

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:45:01

[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 22:06:10
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:15
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4) (b) (4), (b) (6)	21 Dec 2020 10:53:43
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 'Will update' (Site from System).	(b) (4), (b) (6)	10 Dec 2020 19:09:43
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	10 Dec 2020 19:09:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Dec 2020 19:09:31

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:45:01

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:10
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:15
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered '04 Dec 2020'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:09:31

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:45:01

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:10
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:15
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:09:31

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:45:01

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:10
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:15
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:09:31

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:45:01

[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 22:06:10
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:15
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:09:31

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:45:01

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:10
DataPoint Verified.	[REDACTED]	08 Apr 2021 15:51:15
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:09:31

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:45:01

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:10
DataPoint Verified.	(b) (4)	08 Apr 2021 15:51:15
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:09:31

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:45:01

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:10
User entered '1'	System	10 Dec 2020 19:09:31

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:45:01

Did the subject have Respiratory Rates \geq 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:13
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:54
User entered 'No (N)'		10 Dec 2020 19:10:15

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:45:01

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:13
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:54
User entered empty.		10 Dec 2020 19:10:15

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:45:01

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:13
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:54
User entered empty.		10 Dec 2020 19:10:15

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:45:01

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:13
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:54
User entered empty.		10 Dec 2020 19:10:15

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:45:01

[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 22:06:13
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:54
User entered 'No (N)'		10 Dec 2020 19:10:15

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:45:01

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:13
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:54
User entered empty.		10 Dec 2020 19:10:15

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:45:01

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:13
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:54
User entered empty.		10 Dec 2020 19:10:15

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:45:01

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:13
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:54
User entered empty.		10 Dec 2020 19:10:15

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:45:01

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 22:06:13
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:54
User entered 'No (N)'		10 Dec 2020 19:10:15

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:45:01

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:13
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:54
User entered empty.		10 Dec 2020 19:10:15

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:45:01

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:13
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:54
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 19:10:15

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:13
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:54
User entered empty.		10 Dec 2020 19:10:15

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Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:13
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:54
User entered 'No (N)'	(b) (4), (b) (6)	10 Dec 2020 19:10:15

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:45:01

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:13
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:54
User entered empty.		10 Dec 2020 19:10:15

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:45:01

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:13
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:54
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 19:10:15

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Form: Covid-19 Severity Assessment

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:13
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:54
User entered empty.		10 Dec 2020 19:10:15

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Generated On: 11 Aug 2021 22:45:01

[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:13
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:54
User entered 'No (N)'		10 Dec 2020 19:10:15

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:45:01

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:13
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:54
User entered empty.		10 Dec 2020 19:10:15

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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:13
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:54
User entered 'No (N)'		10 Dec 2020 19:10:15

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Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:45:01

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:13
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:54
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 19:10:15

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:13
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:54
User entered empty.		10 Dec 2020 19:10:15

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:45:01

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:13
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:54
User entered empty.		10 Dec 2020 19:10:15

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:45:01

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:13
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:54
User entered empty.		10 Dec 2020 19:10:15

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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:13
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:54
User entered empty.		10 Dec 2020 19:10:15

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:45:01

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:13
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:54
User entered empty.		10 Dec 2020 19:10:15

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:45:01

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:13
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:54
User entered empty.		10 Dec 2020 19:10:15

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Folder: Covid-19 Assessment 03 Dec 2020

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Generated On: 11 Aug 2021 22:45:01

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:13
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:54
User entered empty.		10 Dec 2020 19:10:15

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:45:01

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:13
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:54
User entered empty.		10 Dec 2020 19:10:15

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:45:01

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:13
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:54
User entered empty.		10 Dec 2020 19:10:15

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:45:01

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:13
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:54
User entered empty.		10 Dec 2020 19:10:15

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:45:01

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:13
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:54
User entered empty.		10 Dec 2020 19:10:15

US3472020

Folder: Covid-19 Assessment 03 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:45:01

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:13
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:54
User entered empty.		10 Dec 2020 19:10:15

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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 22:06:13
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User closed query 'Per CDM: Please review both Evidence of Shock and Evidence of Pneumonia sections of this form and update accordingly as it appears to be missing some responses.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 16:00:38
Query 'Per CDM: Please review both Evidence of Shock and Evidence of Pneumonia sections of this form and update accordingly as it appears to be missing some responses.' answered with 'data is accurate' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 14:20:35
User opened query 'Per CDM: Please review both Evidence of Shock and Evidence of Pneumonia sections of this form and update accordingly as it appears to be missing some responses.' (Site from DM).		04 Jan 2021 22:34:02
DataPoint Verified.		24 Dec 2020 04:23:54
User entered 'No (N)'		10 Dec 2020 19:10:15

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Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:13
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:54
User entered empty.		10 Dec 2020 19:10:15

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Folder: Covid-19 Assessment 03 Dec 2020

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:13
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:54
User entered empty.		10 Dec 2020 19:10:15

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Folder: Covid-19 Assessment 03 Dec 2020

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[Evidence of Shock Requires Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:13
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:54
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 19:10:15

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Folder: Covid-19 Assessment 03 Dec 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:13
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:54
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 19:10:15

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:45:01

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:13
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:54
User entered empty.		10 Dec 2020 19:10:15

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[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:13
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:15
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User closed query 'Per CDM: A Yes or No response is required for this question, please update as appropriate.' (Site from DM).	(b) (4)	(b) (4), (b) (6)
Query 'Per CDM: A Yes or No response is required for this question, please update as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 15:10:40
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 18:11:01
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4), (b) (6)	15 Feb 2021 18:10:51
User opened query 'Per CDM: A Yes or No response is required for this question, please update as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 18:10:51
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 16:03:19
User entered empty.	(b) (4), (b) (6)	24 Dec 2020 04:23:54
	(b) (4), (b) (6)	10 Dec 2020 19:10:15

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:45:01

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:13
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:54
User entered empty.		10 Dec 2020 19:10:15

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[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:13
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:15
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User closed query 'Per CDM: A Yes or No response is required for this question, please update as appropriate.' (Site from DM).	(b) (4)	(b) (4), (b) (6)
Query 'Per CDM: A Yes or No response is required for this question, please update as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 15:10:42
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 18:11:05
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4), (b) (6)	15 Feb 2021 18:10:51
User opened query 'Per CDM: A Yes or No response is required for this question, please update as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 16:03:26
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:23:54
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 19:10:15

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Folder: Covid-19 Assessment 03 Dec 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:13
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:54
User entered empty.		10 Dec 2020 19:10:15

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[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:13
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:15
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User closed query 'Per CDM: A Yes or No response is required for this question, please update as appropriate.' (Site from DM).	(b) (4)	(b) (4), (b) (6)
Query 'Per CDM: A Yes or No response is required for this question, please update as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 15:10:46
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 18:11:08
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4), (b) (6)	15 Feb 2021 18:10:51
User opened query 'Per CDM: A Yes or No response is required for this question, please update as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 18:10:51
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 16:03:33
User entered empty.	(b) (4), (b) (6)	24 Dec 2020 04:23:54
	(b) (4), (b) (6)	10 Dec 2020 19:10:15

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:13
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:54
User entered empty.		10 Dec 2020 19:10:15

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[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:13
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:54
User entered 'No (N)'		10 Dec 2020 19:10:15

US3472020

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[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:13
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:54
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 19:10:15

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Generated On: 11 Aug 2021 22:45:01

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:13
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:15
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User closed query 'Per CDM: A Yes or No response is required for this question, please update as appropriate.' (Site from DM).	(b) (4)	(b) (4), (b) (6)
Query 'Per CDM: A Yes or No response is required for this question, please update as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 15:10:50
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 18:11:11
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4), (b) (6)	15 Feb 2021 18:10:51
User opened query 'Per CDM: A Yes or No response is required for this question, please update as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 18:10:51
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 16:03:41
User entered empty.	(b) (4), (b) (6)	24 Dec 2020 04:23:54
	(b) (4), (b) (6)	10 Dec 2020 19:10:15

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[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:13
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:54
User entered empty.		10 Dec 2020 19:10:15

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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 22:06:13
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:54
User entered 'No (N)'		10 Dec 2020 19:10:15

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Folder: Covid-19 Assessment 03 Dec 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:13
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:54
User entered empty.		10 Dec 2020 19:10:15

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:45:01

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:13
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:23:54
User entered empty.		10 Dec 2020 19:10:15

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:45:01

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:18
DataPoint Verified.	(b) (4)	08 Apr 2021 15:51:15
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
	(b) (4)	
User entered 'No (N)'	Jie Ho (b) (4)	07 Jan 2021 03:56:59

US3472020

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:45:01

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	08 Dec 2020 15:10:28

US3472020

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:45:01

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:28:17
User entered 'Yes (Y)'		08 Dec 2020 15:10:28

US3472020

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:45:01

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:28:17
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 08,10,11DEC2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 11:03:56
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 08,10,11DEC2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' ' answered with 'samples collected - EDC updated.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 19:36:15
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 08,10,11DEC2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 09:02:02
User entered '07 Dec 2020'	(b) (4), (b) (6)	08 Dec 2020 15:10:28

US3472020

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:45:01

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	08 Dec 2020 15:10:28

US3472020

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:45:01

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:30:54
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	18 Dec 2020 19:35:23
User entered 'No (N)'	(b) (4), (b) (6)	08 Dec 2020 15:10:28

US3472020

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:45:01

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:30:54
User entered '08 Dec 2020' reason for change: New Information	(b) (4), (b) (6)	18 Dec 2020 19:35:23
User entered empty.	(b) (4), (b) (6)	08 Dec 2020 15:10:28

US3472020

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:45:01

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	08 Dec 2020 15:10:28

US3472020

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:45:01

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4)	24 Dec 2020 04:30:57
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	18 Dec 2020 19:35:39
User entered 'No (N)'		08 Dec 2020 15:10:28

US3472020

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:45:01

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:30:57
User entered '10 Dec 2020' reason for change: New Information	(b) (4), (b) (6)	18 Dec 2020 19:35:39
User entered empty.	(b) (4), (b) (6)	08 Dec 2020 15:10:28

US3472020

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:45:01

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	08 Dec 2020 15:10:28

US3472020

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:45:01

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:31:00
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	18 Dec 2020 19:35:56
User entered 'No (N)'	(b) (4), (b) (6)	08 Dec 2020 15:10:28

US3472020

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:45:01

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User closed query 'Per GCL Lab Reconciliation: Saliva : Sample dated 17DEC2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM). Query 'Per GCL Lab Reconciliation: Saliva : Sample dated 17DEC2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'updated' (Site from DM). User opened query 'Per GCL Lab Reconciliation: Saliva : Sample dated 17DEC2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 06:36:49
User entered '11 Dec 2020' reason for change: New Information User entered empty.		02 Jan 2021 18:09:51
		24 Dec 2020 08:46:49
		24 Dec 2020 04:31:00
		18 Dec 2020 19:35:56
		08 Dec 2020 15:10:28

US3472020

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:45:01

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Collected per source records.. Please confirm/correct for day 14 and day 21 saliva collection. ' (Site from CRA).	(b) (4), (b) (6)	22 Feb 2021 06:44:36
Query 'Collected per source records.. Please confirm/correct for day 14 and day 21 saliva collection. ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	02 Jan 2021 18:09:19
User opened query 'Collected per source records.. Please confirm/correct for day 14 and day 21 saliva collection. ' (Site from CRA).	(b) (4), (b) (6)	24 Dec 2020 04:35:27
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	08 Dec 2020 15:10:28

US3472020

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:45:01

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:07:27
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered 'Yes (Y)' reason for change: New Information	(b) (4)	02 Jan 2021 18:09:14
User entered 'No (N)'	(b) (4), (b) (6)	08 Dec 2020 15:10:28

US3472020

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:45:01

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:07:27
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User closed query 'Per GCL Lab Reconciliation: Saliva : Sample dated 17DEC2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Jan 2021 08:59:53
Query 'Per GCL Lab Reconciliation: Saliva : Sample dated 17DEC2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'Updated, thank you.' (Site from DM).	Jie Ho (b) (4)	05 Jan 2021 15:09:58
User entered '17 Dec 2020' reason for change: New Information	Jie Ho (b) (4)	05 Jan 2021 15:08:50
User opened query 'Per GCL Lab Reconciliation: Saliva : Sample dated 17DEC2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 06:37:05
User entered '21 Dec 2020' reason for change: New Information	(b) (4), (b) (6)	02 Jan 2021 18:09:14
User entered empty.	(b) (4), (b) (6)	08 Dec 2020 15:10:28

US3472020

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:45:01

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	08 Dec 2020 15:10:28

US3472020

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:45:01

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:07:27
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User closed query 'Per Lab Recon: Saliva: Per Preclarus report, Sample dated "23 DEC 2020" is reported under Illness visit "COVID PCR Saliva Day 21" in PPD GCL, however the same is missing in EDC under Illness visit in saliva log Day. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 05:05:17
' (Site from DM). Query 'Per Lab Recon: Saliva: Per Preclarus report, Sample dated "23 DEC 2020" is reported under Illness visit "COVID PCR Saliva Day 21" in PPD GCL, however the same is missing in EDC under Illness visit in saliva log Day. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.	(b) (4), (b) (6)	11 Feb 2021 14:42:42
' answered with 'sample collected, log updated.' (Site from DM). User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 14:42:23
User opened query 'Per Lab Recon: Saliva: Per Preclarus report, Sample dated "23 DEC 2020" is reported under Illness visit "COVID PCR Saliva Day 21" in PPD GCL, however the same is missing in EDC under Illness visit in saliva log Day. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.	(b) (4), (b) (6)	10 Feb 2021 12:40:25
' (Site from DM). User entered 'No (N)'	(b) (4), (b) (6)	08 Dec 2020 15:10:28

US3472020

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:45:01

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:07:27
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User closed query 'Future date has been entered. Please correct.' (Site from System).	(b) (4)	11 Feb 2021 14:42:29
User entered '23 Dec 2020' reason for change: Data Entry Error	System	11 Feb 2021 14:42:29
User opened query 'Future date has been entered. Please correct.' (Site from System).	(b) (4), (b) (6)	11 Feb 2021 14:42:23
User entered '23 Dec 2021' reason for change: Data Entry Error	System	11 Feb 2021 14:42:23
User entered empty.	(b) (4), (b) (6)	08 Dec 2020 15:10:28

US3472020

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:45:01

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	08 Dec 2020 15:10:28

US3472020

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:45:01

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:07:27
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	05 Jan 2021 19:44:38
User entered 'No (N)'	(b) (4), (b) (6)	08 Dec 2020 15:10:28

US3472020

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:45:01

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:07:27
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered '5 Jan 2021' reason for change: Data Entry Error	(b) (4)	05 Jan 2021 19:44:38
User entered empty.	(b) (4), (b) (6)	08 Dec 2020 15:10:28

US3472020

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:45:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:49:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:24:07
User entered 'Yes (Y)'		06 Dec 2020 22:58:22

US3472020

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:49:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:24:07
User entered '04 Dec 2020'		06 Dec 2020 22:58:22

US3472020

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:49:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:24:07
User entered 'Home (Home)'		06 Dec 2020 22:58:22

US3472020

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:45:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:49:12
User entered 'SICKD1'	System	06 Dec 2020 22:58:22

US3472020

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:49:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:24:14
User entered 'Yes (Y)'		06 Dec 2020 22:59:45

US3472020

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:49:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:24:14
User entered '04 Dec 2020'		06 Dec 2020 22:59:45

US3472020

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:49:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:24:14
User entered '14:29'		06 Dec 2020 22:59:45

US3472020

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:49:12
User entered '04 Dec 2020 14:29'	System	06 Dec 2020 22:59:45

US3472020

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:49:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:24:14
User entered missing code ND - Not Done.	(b) (4), (b) (6)	06 Dec 2020 22:59:45
DataPoint set to visible.	System	06 Dec 2020 22:58:22

US3472020

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:49:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:24:14
User entered missing code ND - Not Done.	(b) (4), (b) (6)	06 Dec 2020 22:59:45
DataPoint set to visible.	System	06 Dec 2020 22:58:22

US3472020

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:49:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:24:14
User entered '98.8' F		06 Dec 2020 22:59:45

US3472020

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:49:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:24:14
User entered 'Oral (Oral)'		06 Dec 2020 22:59:45

US3472020

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:49:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:24:14
User entered empty.		06 Dec 2020 22:59:45

US3472020

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:49:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:24:14
User entered '74'		06 Dec 2020 22:59:45

US3472020

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:49:12
User entered 'bpm'	System	06 Dec 2020 22:59:45

US3472020

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:49:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:24:14
User entered '17'	(b) (4), (b) (6)	06 Dec 2020 22:59:45

US3472020

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:49:12
User entered 'breaths/min'	System	06 Dec 2020 22:59:45

US3472020

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:49:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:24:14
User entered '117'		06 Dec 2020 22:59:45

US3472020

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:49:12
User entered 'mmHg'	System	06 Dec 2020 22:59:45

US3472020

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:49:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:24:14
User entered '74'		06 Dec 2020 22:59:45

US3472020

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:49:12
User entered 'mmHg'	System	06 Dec 2020 22:59:45

US3472020

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:49:12

US3472020

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:49:12

US3472020

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:45:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:49:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:24:19
User entered 'Yes (Y)'		06 Dec 2020 22:59:50

US3472020

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:45:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:49:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:24:19
User entered '04 Dec 2020'		06 Dec 2020 22:59:50

US3472020

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:45:01

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:49:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:24:23
User entered 'Yes (Y)'		06 Dec 2020 22:59:56

US3472020

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:45:01

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:49:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4)	24 Dec 2020 04:24:23
User entered '04 Dec 2020'	(b) (4), (b) (6)	06 Dec 2020 22:59:56

US3472020

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:45:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:17:58
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:08:32
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:39:31

US3472020

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:45:01

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:17:58
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:08:32
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered '5 Jan 2021'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:39:31

US3472020

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:17:58
DataPoint Verified.	(b) (4)	31 Mar 2021 13:08:32
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:39:31

US3472020

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:45:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:17:58
User entered 'SICKD28'	System	05 Jan 2021 19:39:31

US3472020

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:18:02
DataPoint Verified.		31 Mar 2021 13:07:04
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:42:06

US3472020

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:18:02
DataPoint Verified.		31 Mar 2021 13:07:04
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered '5 Jan 2021'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:42:06

US3472020

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:18:02
DataPoint Verified.	(b) (4)	31 Mar 2021 13:07:04
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered '11:35'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:42:06

US3472020

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:18:02
User entered '5 Jan 2021 11:35'	System	05 Jan 2021 19:42:06

US3472020

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:18:02
DataPoint Verified.	(b) (4)	31 Mar 2021 13:07:04
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:38:16
User closed query 'Data is required. Please provide.' (Site from System).	System	07 Jan 2021 04:00:36
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	07 Jan 2021 04:00:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Jie Ho (b) (4)	07 Jan 2021 04:00:36
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Jan 2021 19:42:06
User entered empty.	(b) (4), (b) (6)	05 Jan 2021 19:42:06
DataPoint set to visible.	System	05 Jan 2021 19:39:31

US3472020

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:18:02
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:07:04
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:38:16
User closed query 'Data is required. Please provide.' (Site from System).	System	07 Jan 2021 04:00:36
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	07 Jan 2021 04:00:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Jie Ho (b) (4)	07 Jan 2021 04:00:36
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Jan 2021 19:42:06
User entered empty.	(b) (4), (b) (6)	05 Jan 2021 19:42:06
DataPoint set to visible.	System	05 Jan 2021 19:39:31

US3472020

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:18:02
DataPoint Verified.		31 Mar 2021 13:07:04
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered '36.1' C	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:42:06

US3472020

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:18:02
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:07:04
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:42:06

US3472020

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:18:02
DataPoint Verified.	(b) (4)	31 Mar 2021 13:07:04
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:42:06

US3472020

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:18:02
DataPoint Verified.	(b) (4)	31 Mar 2021 13:07:04
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered '68'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:42:06

US3472020

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:18:02
User entered 'bpm'	System	05 Jan 2021 19:42:06

US3472020

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:18:02
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:07:04
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:38:16
User closed query 'Data is required. Please provide.' (Site from System).	System	12 Jan 2021 18:59:57
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	12 Jan 2021 18:59:57
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Jan 2021 18:59:57
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Jan 2021 19:42:06
User entered empty.	(b) (4), (b) (6)	05 Jan 2021 19:42:06

US3472020

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:18:02
User entered 'breaths/min'	System	12 Jan 2021 18:59:57
User entered empty.	System	05 Jan 2021 19:42:06

US3472020

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:18:02
DataPoint Verified.		31 Mar 2021 13:07:04
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered '107'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:42:06

US3472020

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:18:02
User entered 'mmHg'	System	05 Jan 2021 19:42:06

US3472020

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:18:02
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:07:04
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered '72'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:42:06

US3472020

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:18:02
User entered 'mmHg'	System	05 Jan 2021 19:42:06

US3472020

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:18:02

US3472020

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:18:02

US3472020

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:45:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:18:07
DataPoint Verified.		31 Mar 2021 13:07:10
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:42:18

US3472020

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:45:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:18:07
DataPoint Verified.	(b) (4)	31 Mar 2021 13:07:10
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered '5 Jan 2021'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:42:18

US3472020

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:45:01

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:18:12
DataPoint Verified.	(b) (4)	31 Mar 2021 13:07:15
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:42:46

US3472020

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:45:01

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:18:12
DataPoint Verified.	(b) (4)	31 Mar 2021 13:07:15
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered '5 Jan 2021'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:42:46

US3472020

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

Form: Visit Date

Generated On: 11 Aug 2021 22:45:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:16:29
User entered 'Yes (Y)'		05 Feb 2021 19:53:59

US3472020

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

Form: Visit Date

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:16:29
User entered '4 Feb 2021'		05 Feb 2021 19:53:59

US3472020

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

Form: Visit Date

Generated On: 11 Aug 2021 22:45:01

[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 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:16:29
User entered 'Clinic (Clinic)'		05 Feb 2021 19:53:59

US3472020

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

Form: Visit Date

Generated On: 11 Aug 2021 22:45:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User entered 'UNBLND_DECIDE'	System	05 Feb 2021 19:53:59

US3472020

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

Form: Unblinding

Generated On: 11 Aug 2021 22:45:01

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:16:36
User entered '4 Feb 2021'		05 Feb 2021 19:54:42

US3472020

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

Form: Unblinding

Generated On: 11 Aug 2021 22:45:01

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 14:48:14

US3472020

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

Form: Unblinding

Generated On: 11 Aug 2021 22:45:01

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:16:36
User entered 'Yes (Y)'		05 Feb 2021 19:54:42

US3472020

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

Form: Unblinding

Generated On: 11 Aug 2021 22:45:01

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 14:48:14

US3472020

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

Form: Unblinding

Generated On: 11 Aug 2021 22:45:01

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:16:36
User entered '4 Feb 2021'		05 Feb 2021 19:54:42

US3472020

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

Form: Unblinding

Generated On: 11 Aug 2021 22:45:01

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:16:36
User entered 'Placebo (Placebo)'		05 Feb 2021 19:54:42

US3472020

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

Form: Unblinding

Generated On: 11 Aug 2021 22:45:01

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:16:36
User entered 'Placebo (Placebo)'		05 Feb 2021 19:54:42

US3472020

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

Form: Unblinding

Generated On: 11 Aug 2021 22:45:01

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:16:36
User entered 'Placebo (Placebo)'		05 Feb 2021 19:54:42

US3472020

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

Form: Unblinding

Generated On: 11 Aug 2021 22:45:01

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:16:36
User entered 'Yes (Y)'		05 Feb 2021 19:54:42

US3472020

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

Form: Unblinding

Generated On: 11 Aug 2021 22:45:01

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User entered '1'	System	05 Feb 2021 19:54:42

US3472020

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

Form: Unblinding

Generated On: 11 Aug 2021 22:45:01

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User entered '1'	System	05 Feb 2021 19:54:42

US3472020

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:45:01

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:16:44
User entered missing code ND - Not Done.		05 Feb 2021 19:57:22

US3472020

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:45:01

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:16:44
User entered missing code ND - Not Done.		05 Feb 2021 19:57:22

US3472020

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:45:01

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User entered empty.	System	05 Feb 2021 19:57:22
DataPoint set to visible.	System	05 Feb 2021 19:54:42

US3472020

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:45:01

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:16:44
User entered missing code ND - Not Done.		05 Feb 2021 19:57:22

US3472020

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:45:01

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:16:44
User entered missing code ND - Not Done.		05 Feb 2021 19:57:22

US3472020

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:45:01

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User entered empty.	System	05 Feb 2021 19:57:22
DataPoint set to visible.	System	05 Feb 2021 19:54:42

US3472020

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User accepted default value 'Pre-Dose (PREDOSE)'		05 Feb 2021 19:57:22

US3472020

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:16:44
User entered 'Yes (Y)'		05 Feb 2021 19:57:22

US3472020

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:16:44
User entered '4 Feb 2021'		05 Feb 2021 19:57:22

US3472020

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:16:44
User entered '12:04'		05 Feb 2021 19:57:22

US3472020

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User entered '4 Feb 2021 12:04'	System	05 Feb 2021 19:57:22

US3472020

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:16:44
User entered '97.5' F		05 Feb 2021 19:57:22

US3472020

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:16:44
User entered 'Oral (Oral)'		05 Feb 2021 19:57:22

US3472020

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:16:44
User entered empty.		05 Feb 2021 19:57:22

US3472020

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:16:44
User entered '72'		05 Feb 2021 19:57:22

US3472020

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User entered 'bpm'	System	05 Feb 2021 19:57:22

US3472020

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:16:44
User entered '16'		05 Feb 2021 19:57:22

US3472020

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User entered 'breaths/min'	System	05 Feb 2021 19:57:22

US3472020

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:16:44
User entered '107'		05 Feb 2021 19:57:22

US3472020

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User entered 'mmHg'	System	05 Feb 2021 19:57:22

US3472020

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:16:44
User entered '72'		05 Feb 2021 19:57:22

US3472020

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User entered 'mmHg'	System	05 Feb 2021 19:57:22

US3472020

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:45:01

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:16:44
User entered missing code ND - Not Done.		05 Feb 2021 19:57:22

US3472020

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:45:01

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:16:44
User entered missing code ND - Not Done.		05 Feb 2021 19:57:22

US3472020

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:45:01

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User entered empty.	System	05 Feb 2021 19:57:22
DataPoint set to visible.	System	05 Feb 2021 19:54:42

US3472020

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User accepted default value 'Post-Dose (POSTDOSE)'		05 Feb 2021 19:57:22

US3472020

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:16:44
User entered 'Yes (Y)' reason for change: Data Entry Error		09 Feb 2021 18:14:27
User entered 'No (N)'		05 Feb 2021 19:57:22

US3472020

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:16:44
User entered '04 Feb 2021' reason for change: Data Entry Error		09 Feb 2021 18:14:27
User entered empty.		05 Feb 2021 19:57:22

US3472020

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:16:44
User entered '15:05' reason for change: Data Entry Error		09 Feb 2021 18:14:27
User entered empty.		05 Feb 2021 19:57:22

US3472020

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User entered '04 Feb 2021 15:05'	System	09 Feb 2021 18:14:27
User entered empty.	System	05 Feb 2021 19:57:22

US3472020

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:16:44
User entered '98.4' F reason for change: Data Entry Error		09 Feb 2021 18:14:27
User entered empty.		05 Feb 2021 19:57:22

US3472020

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:16:44
User entered 'Oral (Oral)' reason for change: Data Entry Error		09 Feb 2021 18:14:27
User entered empty.		05 Feb 2021 19:57:22

US3472020

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:16:44
User entered empty.		05 Feb 2021 19:57:22

US3472020

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:16:44
User entered '78' reason for change: Data Entry Error		09 Feb 2021 18:14:27
User entered empty.		05 Feb 2021 19:57:22

US3472020

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User entered 'bpm'	System	09 Feb 2021 18:14:27
User entered empty.	System	05 Feb 2021 19:57:22

US3472020

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:16:44
User entered '14' reason for change: Data Entry Error		09 Feb 2021 18:14:27
User entered empty.		05 Feb 2021 19:57:22

US3472020

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User entered 'breaths/min'	System	09 Feb 2021 18:14:27
User entered empty.	System	05 Feb 2021 19:57:22

US3472020

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:16:44
User entered '119' reason for change: Data Entry Error		09 Feb 2021 18:14:27
User entered empty.		05 Feb 2021 19:57:22

US3472020

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User entered 'mmHg'	System	09 Feb 2021 18:14:27
User entered empty.	System	05 Feb 2021 19:57:22

US3472020

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:16:44
User entered '72' reason for change: Data Entry Error		09 Feb 2021 18:14:27
User entered empty.		05 Feb 2021 19:57:22

US3472020

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User entered 'mmHg'	System	09 Feb 2021 18:14:27
User entered empty.	System	05 Feb 2021 19:57:22

US3472020

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:45:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:16:50
User entered 'Yes (Y)'		05 Feb 2021 20:46:29

US3472020

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:45:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:16:50
User entered '04 Feb 2021'		05 Feb 2021 20:46:29

US3472020

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:45:01

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:16:56
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Feb 2021 18:15:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Feb 2021 18:15:16
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 18:15:16
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Feb 2021 19:59:58
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 19:59:58

US3472020

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:45:01

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:16:56
User entered empty.		05 Feb 2021 19:59:58

US3472020

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:45:01

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:16:56
User entered empty.		05 Feb 2021 19:59:58

US3472020

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:45:01

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User entered 'mRNA-1273'	System	09 Feb 2021 18:15:16
User entered empty.	System	05 Feb 2021 19:59:58
DataPoint set to visible.	System	05 Feb 2021 19:54:42

US3472020

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:45:01

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:16:56
User entered '4 Feb 2021'		05 Feb 2021 19:59:58

US3472020

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:45:01

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:16:56
User entered '14:35' reason for change: Data Entry Error		09 Feb 2021 18:15:16
User entered empty.		05 Feb 2021 19:59:58

US3472020

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:45:01

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User entered '4 Feb 2021 14:35'	System	09 Feb 2021 18:15:16
User entered empty.	System	05 Feb 2021 19:59:58

US3472020

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:45:01

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:16:56
User entered 'Right Arm (RIGHT ARM)' reason for change: Data Entry Error		09 Feb 2021 18:15:16
User entered empty.		05 Feb 2021 19:59:58

US3472020

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:45:01

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
DataPoint Verified.		17 Mar 2021 18:16:56
User entered 'ONCE'	System	09 Feb 2021 18:15:16
User entered empty.	System	05 Feb 2021 19:59:58

US3472020

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:45:01

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User entered 'INTRAMUSCULAR'	System	09 Feb 2021 18:15:16
User entered empty.	System	05 Feb 2021 19:59:58

US3472020

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:45:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:17:02
User entered 'Yes (Y)'		05 Feb 2021 20:00:16

US3472020

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:45:01

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:17:02
User entered '4 Feb 2021'		05 Feb 2021 20:00:16

US3472020

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:45:01

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:17:02
User entered '12:15'		05 Feb 2021 20:00:16

US3472020

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:45:01

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User entered '4 Feb 2021 12:15'	System	05 Feb 2021 20:00:16

US3472020

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:45:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:17:07
User entered 'Yes (Y)'		05 Feb 2021 20:00:26

US3472020

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:45:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:17:07
User entered '4 Feb 2021'		05 Feb 2021 20:00:26

US3472020

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:45:01

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:17:07
User entered '12:10'		05 Feb 2021 20:00:26

US3472020

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:45:01

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User entered '4 Feb 2021 12:10'	System	05 Feb 2021 20:00:26

US3472020

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:17:13
User entered 'Yes (Y)'		05 Feb 2021 20:00:30

US3472020

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User entered '1'	System	05 Feb 2021 20:00:30

US3472020

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:17:26
User entered 'Yes (Y)'		12 Feb 2021 18:47:48

US3472020

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:17:26
User entered '12 Feb 2021'		12 Feb 2021 18:47:48

US3472020

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4)	17 Mar 2021 18:17:26
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	12 Feb 2021 18:47:48

US3472020

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:17:26
User entered empty.		12 Feb 2021 18:47:48

US3472020

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:17:32
User entered 'Yes (Y)'		12 Feb 2021 18:48:04

US3472020

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User entered '1'	System	12 Feb 2021 18:48:04

US3472020

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:01

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User entered '1'	System	12 Feb 2021 18:48:04
DataPoint set to visible.	System	12 Feb 2021 18:48:04

US3472020

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:45:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:17:50
User entered 'Yes (Y)'		05 Mar 2021 15:58:25

US3472020

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:45:01

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:17:50
User entered '4 Mar 2021'		05 Mar 2021 15:58:25

US3472020

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:45:01

[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 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:17:50
User entered 'Clinic (Clinic)'		05 Mar 2021 15:58:25

US3472020

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:45:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User entered 'OLD29'	System	05 Mar 2021 15:58:25

US3472020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	05 Mar 2021 15:59:43

US3472020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:17:56
User entered 'Yes (Y)'		05 Mar 2021 15:59:43

US3472020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:17:56
User entered '4 Mar 2021'		05 Mar 2021 15:59:43

US3472020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:17:56
User entered '11:30'		05 Mar 2021 15:59:43

US3472020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User entered '4 Mar 2021 11:30'	System	05 Mar 2021 15:59:43

US3472020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:17:56
User entered '36' C		05 Mar 2021 15:59:43

US3472020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:17:56
User entered 'Oral (Oral)'		05 Mar 2021 15:59:43

US3472020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:17:56
User entered empty.		05 Mar 2021 15:59:43

US3472020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:17:56
User entered '71'		05 Mar 2021 15:59:43

US3472020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User entered 'bpm'	System	05 Mar 2021 15:59:43

US3472020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:17:56
User entered '16'		05 Mar 2021 15:59:43

US3472020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User entered 'breaths/min'	System	05 Mar 2021 15:59:43

US3472020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:17:56
User entered '114'		05 Mar 2021 15:59:43

US3472020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User entered 'mmHg'	System	05 Mar 2021 15:59:43

US3472020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:17:56
User entered '64'		05 Mar 2021 15:59:43

US3472020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User entered 'mmHg'	System	05 Mar 2021 15:59:43

US3472020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User accepted default value 'Post-Dose (POSTDOSE)'		05 Mar 2021 15:59:43

US3472020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:17:56
User entered 'No (N)'		05 Mar 2021 15:59:43

US3472020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:17:56
User entered empty.		05 Mar 2021 15:59:43

US3472020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:17:56
User entered empty.		05 Mar 2021 15:59:43

US3472020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User entered empty.	System	05 Mar 2021 15:59:43

US3472020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:17:56
User entered empty.		05 Mar 2021 15:59:43

US3472020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:17:56
User entered empty.		05 Mar 2021 15:59:43

US3472020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:17:56
User entered empty.		05 Mar 2021 15:59:43

US3472020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:17:56
User entered empty.		05 Mar 2021 15:59:43

US3472020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User entered empty.	System	05 Mar 2021 15:59:43

US3472020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:17:56
User entered empty.		05 Mar 2021 15:59:43

US3472020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User entered empty.	System	05 Mar 2021 15:59:43

US3472020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:17:56
User entered empty.		05 Mar 2021 15:59:43

US3472020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User entered empty.	System	05 Mar 2021 15:59:43

US3472020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:17:56
User entered empty.		05 Mar 2021 15:59:43

US3472020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User entered empty.	System	05 Mar 2021 15:59:43

US3472020

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:45:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:18:01
User entered 'Yes (Y)'		05 Mar 2021 15:59:53

US3472020

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:45:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:18:01
User entered '4 Mar 2021'		05 Mar 2021 15:59:53

US3472020

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:45:01

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:18:23
User entered 'No (N)'		05 Mar 2021 16:01:01

US3472020

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:45:01

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:18:23
User entered 'Physician Decision (PHYSICIAN DECISION)'		05 Mar 2021 16:01:01

US3472020

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:45:01

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:18:23
User entered 'Strong reactogenicity after first open label dose, suspected as r/t previous COVID-19 infection, pt immunity likely comparable to that of two-dose recipient.'		05 Mar 2021 16:01:01

US3472020

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:45:01

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User entered empty.	System	05 Mar 2021 16:01:01
DataPoint set to visible.	System	12 Feb 2021 18:48:04

US3472020

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:45:01

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:18:23
User entered empty.		05 Mar 2021 16:01:01

US3472020

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:45:01

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:18:23
User entered empty.		05 Mar 2021 16:01:01

US3472020

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:45:01

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User entered empty.	System	05 Mar 2021 16:01:01

US3472020

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:45:01

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:18:23
User entered empty.		05 Mar 2021 16:01:01

US3472020

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:45:01

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
DataPoint Verified.		17 Mar 2021 18:18:23
User entered empty.	System	05 Mar 2021 16:01:01

US3472020

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:45:01

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User entered empty.	System	05 Mar 2021 16:01:01

US3472020

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:18:32
User entered 'Yes (Y)'		05 Mar 2021 16:01:09

US3472020

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User entered '1'	System	05 Mar 2021 16:01:09

US3472020

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
DataPoint Verified.	(b) (4)	08 Apr 2021 16:12:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Un-verified.	(b) (4), (b) (6)	17 Mar 2021 18:18:45
DataPoint Verified.	(b) (4)	17 Mar 2021 18:18:38
User entered 'Yes (Y)'	(b) (4)	11 Mar 2021 20:18:32

US3472020

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:01

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
DataPoint Verified.	(b) (4)	08 Apr 2021 16:12:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:18:45
DataPoint Verified.	(b) (4)	17 Mar 2021 18:18:38
User entered '11 Mar 2021'	(b) (4)	11 Mar 2021 20:18:32

US3472020

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:12:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Un-verified.	(b) (4), (b) (6)	17 Mar 2021 18:18:45
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:18:38
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	11 Mar 2021 20:18:32

US3472020

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
DataPoint Verified.	(b) (4)	08 Apr 2021 16:12:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:18:45
DataPoint Verified.	(b) (4)	17 Mar 2021 18:18:38
User entered empty.	(b) (4)	11 Mar 2021 20:18:32

US3472020

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:12:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:18:36

US3472020

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:55:07
User entered 'I'	System	11 Mar 2021 20:18:36

US3472020

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:45:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:51:15
User entered 'Yes (Y)'		05 Apr 2021 20:15:12

US3472020

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:45:01

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4)	08 Apr 2021 15:51:15
User entered '5 Apr 2021'	(b) (4), (b) (6)	05 Apr 2021 20:15:12

US3472020

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:45:01

[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 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:15
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	05 Apr 2021 20:15:12

US3472020

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:45:01

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	05 Apr 2021 20:15:12

US3472020

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4)	08 Apr 2021 15:51:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Apr 2021 20:19:34

US3472020

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:51:15
User entered '5 Apr 2021'		05 Apr 2021 20:19:34

US3472020

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4)	08 Apr 2021 15:51:15
User entered '11:43'	(b) (4), (b) (6)	05 Apr 2021 20:19:34

US3472020

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '5 Apr 2021 11:43'	System	05 Apr 2021 20:19:34

US3472020

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:51:15
User entered '97.7' F		05 Apr 2021 20:19:34

US3472020

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:51:15
User entered 'Oral (Oral)'		05 Apr 2021 20:19:34

US3472020

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:51:15
User entered empty.		05 Apr 2021 20:19:34

US3472020

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:51:15
User entered '78'		05 Apr 2021 20:19:34

US3472020

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	05 Apr 2021 20:19:34

US3472020

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:15
User entered '16'	(b) (4), (b) (6)	05 Apr 2021 20:19:34

US3472020

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	05 Apr 2021 20:19:34

US3472020

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4)	08 Apr 2021 15:51:15
User entered '128'	(b) (4), (b) (6)	05 Apr 2021 20:19:34

US3472020

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Apr 2021 20:19:34

US3472020

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:51:15
User entered '77'		05 Apr 2021 20:19:34

US3472020

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Apr 2021 20:19:34

US3472020

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:45:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:51:15
User entered 'No (N)'		05 Apr 2021 20:19:38

US3472020

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:45:01

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:51:15
User entered empty.		05 Apr 2021 20:19:38

US3472020

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:45:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:51:15
User entered 'Yes (Y)'		05 Apr 2021 20:19:46

US3472020

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:45:01

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4)	08 Apr 2021 15:51:15
User entered '5 Apr 2021'	(b) (4), (b) (6)	05 Apr 2021 20:19:46

US3472020

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:45:01

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:15
User entered '11:45'	(b) (4), (b) (6)	05 Apr 2021 20:19:46

US3472020

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:45:01

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '5 Apr 2021 11:45'	System	05 Apr 2021 20:19:46

US3472020

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:45:01

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:46:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 20:17:21
User entered 'Yes (Y)' reason for change: Data Entry Error		01 Oct 2020 15:02:51
User entered 'No (N)' reason for change: Data Entry Error		09 Sep 2020 03:55:48
User entered 'Yes (Y)'		09 Sep 2020 03:53:47

US3472020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:45:01

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:26

US3472020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:45:01

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:26
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:14
User coded data point as SOC: General disorders and administration site conditions, HLT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 15:05:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 15:05:47
Data point term sent to Coder	System	01 Oct 2020 15:04:14
User entered 'Fatigue'	(b) (4), (b) (6)	01 Oct 2020 15:03:55

US3472020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:45:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:26
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:14
User entered 'No (N)'		01 Oct 2020 15:03:55

US3472020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:45:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:26
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
User closed query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria per Protocol section 8.3.4. This AE started after Day 7 (onwards) post vaccination, review if this is considered as unsolicited event per protocol section 8.3.4. If yes, update this field to "No". Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 22:50:59
Query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria per Protocol section 8.3.4. This AE started after Day 7 (onwards) post vaccination, review if this is considered as unsolicited event per protocol section 8.3.4. If yes, update this field to "No". Else, provide clarification. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	02 Jan 2021 18:55:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Jan 2021 18:55:40
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4), (b) (6)	02 Jan 2021 18:55:40
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User opened query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria per Protocol section 8.3.4. This AE started after Day 7 (onwards) post vaccination, review if this is considered as unsolicited event per protocol section 8.3.4. If yes, update this field to "No". Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	20 Dec 2020 23:51:48
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 01:34:22
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 01:34:22
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:14

US3472020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:45:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 15:03:55

US3472020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:45:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:26
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:14
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 15:03:55

US3472020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:45:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:26
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:14
User entered '29 Sep 2020'		01 Oct 2020 15:03:55

US3472020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:45:01

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:26
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:14
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 15:03:55

US3472020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:45:01

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:26
User entered empty.	System	01 Oct 2020 15:03:55

US3472020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:45:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:26
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:14
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 15:03:55

US3472020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:45:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:26
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:14
User entered '29 Sep 2020'	(b) (4), (b) (6)	01 Oct 2020 15:03:55

US3472020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:45:01

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:26
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:14
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 15:03:55

US3472020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:45:01

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:26
User entered empty.	System	01 Oct 2020 15:03:55

US3472020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:45:01

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:26
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:14
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	01 Oct 2020 15:03:55

US3472020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:45:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:26
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:14
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 15:03:55

US3472020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:45:01

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:26
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:14
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 15:03:55

US3472020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:45:01

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:26
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:14
User entered '0'		01 Oct 2020 15:03:55

US3472020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:45:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:26
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:14
User entered '0'		01 Oct 2020 15:03:55

US3472020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:45:01

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:26
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:14
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 15:03:55

US3472020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:45:01

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:26
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:14
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 15:03:55

US3472020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:45:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:26
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:14
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 15:03:55

US3472020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:45:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:26
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:14
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 15:03:55

US3472020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:45:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:26
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:14
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 15:03:55

US3472020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:45:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:26
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:14
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 15:03:55

US3472020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:45:01

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:26
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:14
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 15:03:55

US3472020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:45:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:26
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:14
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	01 Oct 2020 15:03:55

US3472020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:45:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:26
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:14
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	01 Oct 2020 15:03:55

US3472020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:45:01

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:26
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:14
User entered 'None (NONE)'	(b) (4), (b) (6)	01 Oct 2020 15:03:55

US3472020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:45:01

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:26
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:14
User entered '1'		01 Oct 2020 15:03:55

US3472020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:45:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:26
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:14
User entered '0'		01 Oct 2020 15:03:55

US3472020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:45:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:26
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:14
User entered '0'		01 Oct 2020 15:03:55

US3472020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:45:01

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:26
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:14
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'		01 Oct 2020 15:03:55

US3472020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:45:01

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:26
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:14
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 15:03:55

US3472020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:45:01

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:26
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:14
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 15:03:55

US3472020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:45:01

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:26
User entered '0'	System	01 Oct 2020 15:03:55

US3472020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:45:01

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:26
User entered '0'	System	01 Oct 2020 15:03:55

US3472020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:45:01

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:26

US3472020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:45:01

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:30

US3472020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:45:01

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:30
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User closed query 'Per DM CLR: Please review and update AE term to reflect the specific body location and type of MYALGIA. Please reconcile with the ConMed eCRF so there is an appropriate match. ' (Site from DM).		20 Nov 2020 07:05:16
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Myalgia - version MedDRA\23.0.	Coder Import (b) (4)	13 Nov 2020 15:50:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	13 Nov 2020 15:50:46
Data point term sent to Coder	System	13 Nov 2020 15:49:28
Query 'Per DM CLR: Please review and update AE term to reflect the specific body location and type of MYALGIA. Please reconcile with the ConMed eCRF so there is an appropriate match. ' answered with 'Updated.' (Site from DM).	Jie Ho (b) (4)	13 Nov 2020 15:49:24
DataPoint Un-verified.	Jie Ho (b) (4)	13 Nov 2020 15:49:17
Coding entries removed.	Jie Ho (b) (4)	13 Nov 2020 15:49:17
User entered 'GENERALIZED MYALGIA' reason for change: Per Query Resolution	Jie Ho (b) (4)	13 Nov 2020 15:49:17
User opened query 'Per DM CLR: Please review and update AE term to reflect the specific body location and type of MYALGIA. Please reconcile with the ConMed eCRF so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 00:30:32
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:14
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Myalgia - version MedDRA\23.0.	Coder Import (b) (4)	01 Oct 2020 15:07:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	01 Oct 2020 15:07:47
Data point term sent to Coder	System	01 Oct 2020 15:07:23

US3472020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:45:01

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'Myalgia'	(b) (4), (b) (6)	01 Oct 2020 15:06:36

US3472020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:45:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:30
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:14
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 15:06:36

US3472020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:45:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:30
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
User closed query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria per Protocol section 8.3.4. This AE started after Day 7 (onwards) post vaccination, review if this is considered as unsolicited event per protocol section 8.3.4. If yes, update this field to "No". Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 22:52:14
Query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria per Protocol section 8.3.4. This AE started after Day 7 (onwards) post vaccination, review if this is considered as unsolicited event per protocol section 8.3.4. If yes, update this field to "No". Else, provide clarification. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	02 Jan 2021 18:56:04
DataPoint Un-verified.	(b) (4), (b) (6)	02 Jan 2021 18:56:00
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4), (b) (6)	02 Jan 2021 18:56:00
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User opened query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria per Protocol section 8.3.4. This AE started after Day 7 (onwards) post vaccination, review if this is considered as unsolicited event per protocol section 8.3.4. If yes, update this field to "No". Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	20 Dec 2020 23:52:03
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 01:34:37
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 01:34:37
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:14

US3472020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:45:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 15:06:36

US3472020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:45:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:30
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:14
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 15:06:36

US3472020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:45:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:30
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:14
User entered '29 Sep 2020'	(b) (4), (b) (6)	01 Oct 2020 15:06:36

US3472020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:45:01

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:30
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:14
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 15:06:36

US3472020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:45:01

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:30
User entered empty.	System	01 Oct 2020 15:06:36

US3472020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:45:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:30
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:14
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 15:06:36

US3472020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:45:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:30
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:14
User entered '29 Sep 2020'	(b) (4), (b) (6)	01 Oct 2020 15:06:36

US3472020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:45:01

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:30
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:14
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 15:06:36

US3472020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:45:01

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:30
User entered empty.	System	01 Oct 2020 15:06:36

US3472020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:45:01

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:30
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:14
User entered 'Grade 1/Mild (Grade 1/Mild)'		01 Oct 2020 15:06:36

US3472020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:45:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:30
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:14
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 15:06:36

US3472020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:45:01

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:30
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:14
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 15:06:36

US3472020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:45:01

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:30
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:14
User entered '0'		01 Oct 2020 15:06:36

US3472020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:45:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:30
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:14
User entered '0'		01 Oct 2020 15:06:36

US3472020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:45:01

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:30
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:14
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 15:06:36

US3472020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:45:01

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:30
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:14
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 15:06:36

US3472020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:45:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:30
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:14
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 15:06:36

US3472020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:45:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:30
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:14
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 15:06:36

US3472020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:45:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:30
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:14
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 15:06:36

US3472020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:45:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:30
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:14
User entered '0'		01 Oct 2020 15:06:36

US3472020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:45:01

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:30
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:14
User entered '0'		01 Oct 2020 15:06:36

US3472020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:45:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:30
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:14
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	01 Oct 2020 15:06:36

US3472020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:45:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:30
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:14
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	01 Oct 2020 15:06:36

US3472020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:45:01

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:30
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:14
User entered 'None (NONE)'		01 Oct 2020 15:06:36

US3472020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:45:01

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:30
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:14
User entered '1'		01 Oct 2020 15:06:36

US3472020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:45:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:30
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:14
User entered '0'		01 Oct 2020 15:06:36

US3472020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:45:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:30
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:14
User entered '0'		01 Oct 2020 15:06:36

US3472020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:45:01

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:30
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:14
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'		01 Oct 2020 15:06:36

US3472020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:45:01

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:30
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:14
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 15:06:36

US3472020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:45:01

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:30
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:14
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 15:06:36

US3472020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:45:01

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:30
User entered '0'	System	01 Oct 2020 15:06:36

US3472020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:45:01

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:30
User entered '0'	System	01 Oct 2020 15:06:36

US3472020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:45:01

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:30

US3472020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:01

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:36

US3472020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:01

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:36
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User closed query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).'(Site from DM).	(b) (4) (b) (4), (b) (6)	02 Feb 2021 12:19:12
Query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).'answered with 'Per clinician, result of participant dietary changes.'(Site from DM).	(b) (4), (b) (6)	01 Feb 2021 15:44:43
User opened query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).'(Site from DM).	(b) (4), (b) (6)	01 Feb 2021 14:55:23
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal motility and defaecation conditions, HLT: Diarrhoea (excl infective), PT: Diarrhoea, LLT: Diarrhea - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 19:06:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 19:06:38
Data point term sent to Coder	System	21 Oct 2020 19:05:13
User entered 'diarrhea'	(b) (4), (b) (6)	21 Oct 2020 19:04:47

US3472020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:36
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered 'No (N)'	(b) (4), (b) (6)	21 Oct 2020 19:04:47

US3472020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:36
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User closed query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' (Site from DM).	(b) (4)	20 Nov 2020 07:04:59
Query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' answered with 'Updated, thank you.' (Site from DM).	Jie Ho (b) (4)	11 Nov 2020 20:20:02
User entered 'No (N)' reason for change: Per Query Resolution	Jie Ho (b) (4)	11 Nov 2020 20:19:53
User opened query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 07:29:00
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 01:34:50
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Nov 2020 20:52:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Oct 2020 19:04:47

US3472020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:36
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered 'No (N)'		21 Oct 2020 19:04:47

US3472020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:36
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered '18 Oct 2020'		21 Oct 2020 19:04:47

US3472020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:01

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:36
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 19:04:47

US3472020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:01

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:36
User entered empty.	System	21 Oct 2020 19:04:47

US3472020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:36
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
DataPoint Un-verified.	(b) (4), (b) (6)	02 Jan 2021 15:47:01
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	02 Jan 2021 15:47:01
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Oct 2020 19:04:47

US3472020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:36
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	02 Jan 2021 15:47:24
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	02 Jan 2021 15:47:24
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	02 Jan 2021 15:47:01
DataPoint Un-verified.	(b) (4), (b) (6)	02 Jan 2021 15:47:01
User entered '23 Dec 2020' reason for change: New Information	(b) (4), (b) (6)	02 Jan 2021 15:47:01
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 19:04:47

US3472020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:01

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:36
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 19:04:47

US3472020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:01

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:36
User entered empty.	System	21 Oct 2020 19:04:47

US3472020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:01

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:36
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	21 Oct 2020 19:04:47

US3472020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:36
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered 'No (N)'		21 Oct 2020 19:04:47

US3472020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:01

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:36
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered '0'		21 Oct 2020 19:04:47

US3472020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:01

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:36
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered '0'		21 Oct 2020 19:04:47

US3472020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:36
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered '0'		21 Oct 2020 19:04:47

US3472020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:01

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:36
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 19:04:47

US3472020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:01

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:36
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 19:04:47

US3472020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:36
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 19:04:47

US3472020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:36
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 19:04:47

US3472020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:36
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered '0'		21 Oct 2020 19:04:47

US3472020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:36
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered '0'		21 Oct 2020 19:04:47

US3472020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:01

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:36
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered '0'		21 Oct 2020 19:04:47

US3472020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:36
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	21 Oct 2020 19:04:47

US3472020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:36
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered 'Not Related (NOT RELATED)'		21 Oct 2020 19:04:47

US3472020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:01

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:36
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered 'None (NONE)'	(b) (4), (b) (6)	21 Oct 2020 19:04:47

US3472020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:01

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:36
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered '1'		21 Oct 2020 19:04:47

US3472020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:36
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered '0'		21 Oct 2020 19:04:47

US3472020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:36
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered '0'		21 Oct 2020 19:04:47

US3472020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:01

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:36
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
DataPoint Un-verified.	(b) (4), (b) (6)	02 Jan 2021 15:47:24
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4), (b) (6)	02 Jan 2021 15:47:24
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	21 Oct 2020 19:04:47

US3472020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:01

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:36
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 19:04:47

US3472020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:01

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:36
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered 'Participant has changed diet' reason for change: Data Entry Error		22 Oct 2020 14:29:54
User entered empty.		21 Oct 2020 19:04:47

US3472020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:01

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:36
User entered '0'	System	21 Oct 2020 19:04:47

US3472020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:01

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:36
User entered '0'	System	21 Oct 2020 19:04:47

US3472020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:01

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:36

US3472020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:45:01

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:41

US3472020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:45:01

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:41
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
User coded data point as SOC: Nervous system disorders, HLG: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Intermittent headache - version MedDRA\23.0.	Coder Import (b) (4)	08 Feb 2021 20:55:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	08 Feb 2021 20:55:36
Data point term sent to Coder	System	08 Feb 2021 20:24:04
DataPoint Un-verified.	(b) (4), (b) (6)	08 Feb 2021 20:24:00
Coding entries removed.	(b) (4), (b) (6)	08 Feb 2021 20:24:00
User entered 'HEADACHE, intermittent' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Feb 2021 20:24:00
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User coded data point as SOC: Nervous system disorders, HLG: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\23.0.	Coder Import (b) (4)	22 Oct 2020 14:32:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	22 Oct 2020 14:32:36
Data point term sent to Coder	System	22 Oct 2020 14:31:44
User entered 'Headache'	(b) (4), (b) (6)	22 Oct 2020 14:31:19

US3472020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:45:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:41
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered 'No (N)'	(b) (4), (b) (6)	22 Oct 2020 14:31:19

US3472020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:45:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:41
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
User closed query 'Per DM CLR: Note, this is a solicited adverse reaction per protocol section 8.3.4. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to "YES". Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 16:09:09
Query 'Per DM CLR: Note, this is a solicited adverse reaction per protocol section 8.3.4. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to "YES". Otherwise, clarify.' answered with 'updated field to YES' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 20:18:24
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Feb 2021 20:18:12
User opened query 'Per DM CLR: Note, this is a solicited adverse reaction per protocol section 8.3.4. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to "YES". Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 06:58:00
DataPoint Un-verified.	(b) (4), (b) (6)	02 Jan 2021 19:00:53
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Jan 2021 19:00:53
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Oct 2020 14:31:19

US3472020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:45:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:41
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered 'No (N)'		22 Oct 2020 14:31:19

US3472020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:45:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:41
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
User closed query 'Per DM CLR - RQ: Site's response noted. However, per eDiary, it seems that this is a continuation from the 7 Days Post vaccination recording. Please note that when eDiary symptom are recorded as AE, the start date should be the date when the symptom was initially recorded in the eDiary. The initial start date Solicited Symptom HEADACHE is 08SEP2020 on eDiary. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 16:09:17
Query 'Per DM CLR - RQ: Site's response noted. However, per eDiary, it seems that this is a continuation from the 7 Days Post vaccination recording. Please note that when eDiary symptom are recorded as AE, the start date should be the date when the symptom was initially recorded in the eDiary. The initial start date Solicited Symptom HEADACHE is 08SEP2020 on eDiary. Please review if this should be reconciled. Else, provide clarification on dates.' answered with 'reconciled.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 20:19:03
DataPoint Un-verified.	(b) (4), (b) (6)	08 Feb 2021 20:18:12
User entered '08 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Feb 2021 20:18:12
User opened query 'Per DM CLR - RQ: Site's response noted. However, per eDiary, it seems that this is a continuation from the 7 Days Post vaccination recording. Please note that when eDiary symptom are recorded as AE, the start date should be the date when the symptom was initially recorded in the eDiary. The initial start date Solicited Symptom HEADACHE is 08SEP2020 on eDiary. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 06:57:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:45:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom HEADACHE on 08SEP2020. Please review if this should be reconciled. Else, provide clarification on dates. ' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 03:17:32
Query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom HEADACHE on 08SEP2020. Please review if this should be reconciled. Else, provide clarification on dates. ' answered with 'Separate AE - EDC updated' (Site from DM).	(b) (4), (b) (6)	02 Jan 2021 19:01:39
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User opened query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom HEADACHE on 08SEP2020. Please review if this should be reconciled. Else, provide clarification on dates. ' (Site from DM).	(b) (4), (b) (6)	20 Dec 2020 23:52:52
User entered '15 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Nov 2020 20:51:44
User entered '15 Oct 2020'	(b) (4), (b) (6)	22 Oct 2020 14:31:19

US3472020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:45:01

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:41
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Feb 2021 20:19:14
DataPoint Un-verified.	(b) (4), (b) (6)	08 Feb 2021 20:19:14
User entered '21:00' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Feb 2021 20:19:14
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Feb 2021 20:18:12
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 14:31:19

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:45:01

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:41
User entered '08 Sep 2020 21:00'	System	08 Feb 2021 20:19:14
User entered empty.	System	22 Oct 2020 14:31:19

US3472020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:45:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:41
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered 'No (N)'		22 Oct 2020 14:31:19

US3472020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:45:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:41
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered '16 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Nov 2020 20:51:44
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	22 Oct 2020 14:31:34
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	22 Oct 2020 14:31:34
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	22 Oct 2020 14:31:19
User entered '16 Oct 2020'	(b) (4), (b) (6)	22 Oct 2020 14:31:19

US3472020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:45:01

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:41
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Feb 2021 20:22:31
DataPoint Un-verified.	(b) (4), (b) (6)	08 Feb 2021 20:22:31
User entered '10:00' reason for change: New Information	(b) (4), (b) (6)	08 Feb 2021 20:22:31
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Feb 2021 20:18:12
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 14:31:19

US3472020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:45:01

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:41
User entered '16 Sep 2020 10:00'	System	08 Feb 2021 20:22:31
User entered empty.	System	22 Oct 2020 14:31:19

US3472020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:45:01

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:41
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered 'Grade 1/Mild (Grade 1/Mild)'		22 Oct 2020 14:31:19

US3472020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:45:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:41
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered 'No (N)'		22 Oct 2020 14:31:19

US3472020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:45:01

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:41
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered '0'		22 Oct 2020 14:31:19

US3472020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:45:01

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:41
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered '0'		22 Oct 2020 14:31:19

US3472020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:45:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:41
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered '0'		22 Oct 2020 14:31:19

US3472020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:45:01

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:41
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 14:31:19

US3472020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:45:01

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:41
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 14:31:19

US3472020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:45:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:41
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 14:31:19

US3472020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:45:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:41
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 14:31:19

US3472020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:45:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:41
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered '0'		22 Oct 2020 14:31:19

US3472020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:45:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:41
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered '0'		22 Oct 2020 14:31:19

US3472020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:45:01

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:41
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered '0'		22 Oct 2020 14:31:19

US3472020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:45:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:41
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered 'Related (RELATED)'		22 Oct 2020 14:31:19

US3472020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:45:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:41
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered 'Not Related (NOT RELATED)'		22 Oct 2020 14:31:19

US3472020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:45:01

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:41
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Oct 2020 14:31:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Oct 2020 14:31:34
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 14:31:34
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Oct 2020 14:31:19
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 14:31:19

US3472020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:45:01

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:41
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered 'l'		22 Oct 2020 14:31:19

US3472020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:45:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:41
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered '0'		22 Oct 2020 14:31:19

US3472020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:45:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:41
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered '0'		22 Oct 2020 14:31:19

US3472020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:45:01

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:41
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4)	22 Oct 2020 14:31:34
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4)	22 Oct 2020 14:31:19

US3472020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:45:01

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:41
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered empty.		22 Oct 2020 14:31:19

US3472020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:45:01

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:41
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 14:31:19

US3472020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:45:01

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:41
User entered '0'	System	22 Oct 2020 14:31:19

US3472020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:45:01

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:41
User entered '0'	System	22 Oct 2020 14:31:19

US3472020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:45:01

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:41

US3472020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:01

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:46

US3472020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:01

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Knee pain - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 01:31:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 01:31:37
Data point term sent to Coder	System	05 Nov 2020 01:30:36
User entered 'Knee pain'	(b) (4), (b) (6)	05 Nov 2020 01:30:23

US3472020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 01:30:23

US3472020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered 'No (N)'		05 Nov 2020 01:30:23

US3472020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered 'No (N)'		05 Nov 2020 01:30:23

US3472020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered '21 Oct 2020'		05 Nov 2020 01:30:23

US3472020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:01

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 01:30:23

US3472020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:01

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:46
User entered empty.	System	05 Nov 2020 01:30:23

US3472020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
DataPoint Un-verified.	(b) (4)	02 Jan 2021 15:47:58
User entered 'No (N)' reason for change: New Information	(b) (4)	02 Jan 2021 15:47:58
DataPoint Verified.	(b) (4)	24 Dec 2020 04:17:44
User entered 'Yes (Y)'	(b) (4)	05 Nov 2020 01:30:23

US3472020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
DataPoint Un-verified.		02 Jan 2021 15:47:58
User entered '23 Dec 2020' reason for change: New Information		02 Jan 2021 15:47:58
DataPoint Verified.		24 Dec 2020 04:17:44
User entered empty.		05 Nov 2020 01:30:23

US3472020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:01

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 01:30:23

US3472020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:01

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:46
User entered empty.	System	05 Nov 2020 01:30:23

US3472020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:01

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered 'Grade 1/Mild (Grade 1/Mild)'		05 Nov 2020 01:30:23

US3472020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered 'No (N)'		05 Nov 2020 01:30:23

US3472020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:01

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered '0'		05 Nov 2020 01:30:23

US3472020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:01

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered '0'		05 Nov 2020 01:30:23

US3472020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered '0'		05 Nov 2020 01:30:23

US3472020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:01

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 01:30:23

US3472020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:01

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 01:30:23

US3472020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 01:30:23

US3472020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 01:30:23

US3472020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered '0'		05 Nov 2020 01:30:23

US3472020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered '0'		05 Nov 2020 01:30:23

US3472020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:01

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered '0'		05 Nov 2020 01:30:23

US3472020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 01:30:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Nov 2020 01:30:48
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 01:30:48
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 01:30:23
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 01:30:23

US3472020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 01:30:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Nov 2020 01:30:48
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 01:30:48
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 01:30:23
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 01:30:23

US3472020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:01

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 01:30:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Nov 2020 01:30:48
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 01:30:48
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 01:30:23
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 01:30:23

US3472020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:01

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	05 Nov 2020 01:30:48
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 01:30:48
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	05 Nov 2020 01:30:23
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 01:30:23

US3472020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered '0'		05 Nov 2020 01:30:23

US3472020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered '0'		05 Nov 2020 01:30:23

US3472020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:01

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
DataPoint Un-verified.	(b) (4), (b) (6)	02 Jan 2021 15:47:58
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4), (b) (6)	02 Jan 2021 15:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	05 Nov 2020 01:30:23

US3472020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:01

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 01:30:23

US3472020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:01

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered 'pain in knee joint'	(b) (4), (b) (6)	05 Nov 2020 01:30:23

US3472020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:01

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:46
User entered '0'	System	05 Nov 2020 01:30:23

US3472020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:01

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:46
User entered '0'	System	05 Nov 2020 01:30:23

US3472020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:01

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:46

US3472020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:45:01

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:52
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 16:16:12
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 13:26:10

US3472020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:45:01

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:52
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User closed query 'Per MM, please update term to specify cause or underlying diagnosis versus symptom if known. If underlying diagnosis is already recorded as an adverse event, recording of its symptoms is not required and the AE may be deleted.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 12:41:45
Query 'Per MM, please update term to specify cause or underlying diagnosis versus symptom if known. If underlying diagnosis is already recorded as an adverse event, recording of its symptoms is not required and the AE may be deleted.' answered with 'No alternative etiology known for symptom.' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 19:33:19
User opened query 'Per MM, please update term to specify cause or underlying diagnosis versus symptom if known. If underlying diagnosis is already recorded as an adverse event, recording of its symptoms is not required and the AE may be deleted.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 14:55:46
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Coughing and associated symptoms, PT: Productive cough, LLT: Productive cough - version MedDRA\23.0.	Coder Import (b) (4)	05 Nov 2020 04:43:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	05 Nov 2020 04:43:44
Data point term sent to Coder	System	05 Nov 2020 01:32:37
User entered 'wet cough'	(b) (4), (b) (6)	05 Nov 2020 01:32:31

US3472020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:45:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:52
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered 'No (N)'		05 Nov 2020 01:32:31

US3472020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:45:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:52
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 01:32:31

US3472020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:45:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:52
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User closed query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No. ' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 13:59:52
Query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No. ' answered with 'Updated, thank you.' (Site from Safety).	Jie Ho (b) (4)	05 Nov 2020 15:49:55
User entered 'No (N)' reason for change: Data Entry Error	Jie Ho (b) (4)	05 Nov 2020 15:49:41
User opened query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No. ' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 13:26:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 01:32:31

US3472020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:45:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:52
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered '3 Nov 2020'		05 Nov 2020 01:32:31

US3472020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:45:01

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:52
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 01:32:31

US3472020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:45:01

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:52
User entered empty.	System	05 Nov 2020 01:32:31

US3472020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:45:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:52
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
DataPoint Un-verified.		02 Jan 2021 15:48:38
User entered 'No (N)' reason for change: New Information		02 Jan 2021 15:48:38
DataPoint Verified.		24 Dec 2020 04:17:44
User entered 'Yes (Y)'		05 Nov 2020 01:32:31

US3472020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:45:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:52
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
DataPoint Un-verified.		02 Jan 2021 15:48:38
User entered '23 Dec 2020' reason for change: New Information		02 Jan 2021 15:48:38
DataPoint Verified.		24 Dec 2020 04:17:44
User entered empty.		05 Nov 2020 01:32:31

US3472020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:45:01

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:52
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 01:32:31

US3472020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:45:01

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:52
User entered empty.	System	05 Nov 2020 01:32:31

US3472020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:45:01

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:52
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	05 Nov 2020 01:32:31

US3472020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:45:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:52
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 01:32:31

US3472020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:45:01

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:52
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered '0'		05 Nov 2020 01:32:31

US3472020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:45:01

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:52
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered '0'		05 Nov 2020 01:32:31

US3472020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:45:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:52
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered '0'		05 Nov 2020 01:32:31

US3472020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:45:01

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:52
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 01:32:31

US3472020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:45:01

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:52
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 01:32:31

US3472020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:45:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:52
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 01:32:31

US3472020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:45:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:52
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 01:32:31

US3472020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:45:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:52
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered '0'		05 Nov 2020 01:32:31

US3472020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:45:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:52
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered '0'		05 Nov 2020 01:32:31

US3472020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:45:01

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:52
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 01:32:31

US3472020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:45:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:52
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered 'Not Related (NOT RELATED)'		05 Nov 2020 01:32:31

US3472020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:45:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:52
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	05 Nov 2020 01:32:31

US3472020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:45:01

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:52
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	05 Nov 2020 01:32:31

US3472020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:45:01

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:52
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered '1'		05 Nov 2020 01:32:31

US3472020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:45:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:52
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered '0'		05 Nov 2020 01:32:31

US3472020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:45:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:52
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered '0'		05 Nov 2020 01:32:31

US3472020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:45:01

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:52
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
DataPoint Un-verified.	(b) (4), (b) (6)	02 Jan 2021 15:48:38
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4), (b) (6)	02 Jan 2021 15:48:38
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	05 Nov 2020 01:32:31

US3472020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:45:01

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:52
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 01:32:31

US3472020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:45:01

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:52
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 01:32:31

US3472020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:45:01

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:52
User entered '0'	System	05 Nov 2020 01:32:31

US3472020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:45:01

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:52
User entered '0'	System	05 Nov 2020 01:32:31

US3472020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:45:01

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:52

US3472020

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 11 Aug 2021 22:45:01

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:17:44
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 16:16:12
User entered 'USA-US122-2020-mRNA-1273-P301000005'	System	11 Dec 2020 16:15:42
User entered 'New'	(b) (4), (b) (6)	11 Dec 2020 16:15:42

US3472020

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 11 Aug 2021 22:45:01

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:17:44
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 19:14:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 19:14:55
Data point term sent to Coder	System	10 Dec 2020 19:14:41
User entered 'COVID-19'	(b) (4), (b) (6)	10 Dec 2020 19:13:51

US3472020

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 11 Aug 2021 22:45:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered 'Yes (Y)'	(b) (4)	10 Dec 2020 19:13:51

US3472020

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 11 Aug 2021 22:45:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered 'No (N)'		10 Dec 2020 19:13:51

US3472020

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 11 Aug 2021 22:45:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Dec 2020 19:13:51

US3472020

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 11 Aug 2021 22:45:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered '03 Dec 2020'	(b) (4), (b) (6)	10 Dec 2020 19:13:51

US3472020

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 11 Aug 2021 22:45:01

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 19:13:51

US3472020

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 11 Aug 2021 22:45:01

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Dec 2020 19:13:51

US3472020

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 11 Aug 2021 22:45:01

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered 'No (N)' reason for change: Data Entry Error		21 Dec 2020 20:15:11
User entered 'Yes (Y)'		10 Dec 2020 19:13:51

US3472020

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 11 Aug 2021 22:45:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:17:44
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	22 Dec 2020 21:00:08
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'updated' (Site from Safety).		21 Dec 2020 20:15:20
User entered '18 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Dec 2020 20:15:11
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).		17 Dec 2020 19:17:16
User entered empty.		10 Dec 2020 19:13:51

US3472020

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 11 Aug 2021 22:45:01

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered empty.		10 Dec 2020 19:13:51

US3472020

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 11 Aug 2021 22:45:01

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Dec 2020 19:13:51

US3472020

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 11 Aug 2021 22:45:01

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered 'Grade 2/Moderate (Grade 2/Moderate)'		10 Dec 2020 19:13:51

US3472020

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 11 Aug 2021 22:45:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered 'No (N)'	(b) (4)	10 Dec 2020 19:13:51

US3472020

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 11 Aug 2021 22:45:01

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered '0'		10 Dec 2020 19:13:51

US3472020

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 11 Aug 2021 22:45:01

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered '0'	(b) (4), (b) (6)	10 Dec 2020 19:13:51

US3472020

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 11 Aug 2021 22:45:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered '0'		10 Dec 2020 19:13:51

US3472020

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 11 Aug 2021 22:45:01

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered empty.		10 Dec 2020 19:13:51

US3472020

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 11 Aug 2021 22:45:01

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 19:13:51

US3472020

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 11 Aug 2021 22:45:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered empty.	(b) (4)	10 Dec 2020 19:13:51

US3472020

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 11 Aug 2021 22:45:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered empty.	(b) (4)	10 Dec 2020 19:13:51

US3472020

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 11 Aug 2021 22:45:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered '0'		10 Dec 2020 19:13:51

US3472020

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 11 Aug 2021 22:45:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered '0'		10 Dec 2020 19:13:51

US3472020

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 11 Aug 2021 22:45:01

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered '0'	(b) (4), (b) (6)	10 Dec 2020 19:13:51

US3472020

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 11 Aug 2021 22:45:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered 'Not Related (NOT RELATED)'		10 Dec 2020 19:13:51

US3472020

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 11 Aug 2021 22:45:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	10 Dec 2020 19:13:51

US3472020

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 11 Aug 2021 22:45:01

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered 'Not Applicable (NOT APPLICABLE)'		10 Dec 2020 19:13:51

US3472020

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 11 Aug 2021 22:45:01

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered '0'	(b) (4), (b) (6)	10 Dec 2020 19:13:51

US3472020

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 11 Aug 2021 22:45:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered '1'		10 Dec 2020 19:13:51

US3472020

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 11 Aug 2021 22:45:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered '0'		10 Dec 2020 19:13:51

US3472020

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 11 Aug 2021 22:45:01

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4)	24 Dec 2020 04:17:44
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	22 Dec 2020 20:59:56
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)	21 Dec 2020 20:15:27
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Dec 2020 20:15:11
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)	17 Dec 2020 19:16:58
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	10 Dec 2020 19:13:51

US3472020

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 11 Aug 2021 22:45:01

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User entered empty.	(b) (4)	10 Dec 2020 19:13:51

US3472020

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 11 Aug 2021 22:45:01

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 15:19:20
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'conmed taken - listed in conmed log' (Site from Safety).	(b) (4), (b) (6)	02 Jan 2021 19:07:26
DataPoint Un-verified.	(b) (4), (b) (6)	02 Jan 2021 19:07:13
User entered 'Acetaminophen taken for treatment' reason for change: Per Query Resolution	(b) (4), (b) (6)	02 Jan 2021 19:07:13
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:17:44
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 19:17:34
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 19:13:51

US3472020

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 11 Aug 2021 22:45:01

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	10 Dec 2020 19:13:51

US3472020

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 11 Aug 2021 22:45:01

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	10 Dec 2020 19:13:51

US3472020

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 11 Aug 2021 22:45:01

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:01

US3472020

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 11 Aug 2021 22:45:01

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Oropharyngeal pain, LLT: Sore throat - version MedDRA\23.0.	Coder Import (b) (4)	17 Feb 2021 20:43:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	17 Feb 2021 20:43:03
Data point term sent to Coder	System	17 Feb 2021 20:42:44
User entered 'sore throat'	(b) (4), (b) (6)	17 Feb 2021 20:42:24

US3472020

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 11 Aug 2021 22:45:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
User entered 'No (N)'	(b) (4), (b) (6)	17 Feb 2021 20:42:24

US3472020

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 11 Aug 2021 22:45:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
User entered 'No (N)'		17 Feb 2021 20:42:24

US3472020

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 11 Aug 2021 22:45:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
User entered 'No (N)'		17 Feb 2021 20:42:24

US3472020

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 11 Aug 2021 22:45:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
User entered '18 Jan 2021'		17 Feb 2021 20:42:24

US3472020

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 11 Aug 2021 22:45:01

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
User entered empty.	(b) (4), (b) (6)	17 Feb 2021 20:42:24

US3472020

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 11 Aug 2021 22:45:01

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:01
User entered empty.	System	17 Feb 2021 20:42:24

US3472020

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 11 Aug 2021 22:45:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
User entered 'No (N)'		17 Feb 2021 20:42:24

US3472020

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 11 Aug 2021 22:45:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
User entered '20 Jan 2021'		17 Feb 2021 20:42:24

US3472020

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 11 Aug 2021 22:45:01

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
User entered empty.	(b) (4), (b) (6)	17 Feb 2021 20:42:24

US3472020

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 11 Aug 2021 22:45:01

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:01
User entered empty.	System	17 Feb 2021 20:42:24

US3472020

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 11 Aug 2021 22:45:01

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	17 Feb 2021 20:42:24

US3472020

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 11 Aug 2021 22:45:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
User entered 'No (N)'	(b) (4), (b) (6)	17 Feb 2021 20:42:24

US3472020

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 11 Aug 2021 22:45:01

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
User entered '0'		17 Feb 2021 20:42:24

US3472020

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 11 Aug 2021 22:45:01

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
User entered '0'		17 Feb 2021 20:42:24

US3472020

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 11 Aug 2021 22:45:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
User entered '0'		17 Feb 2021 20:42:24

US3472020

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 11 Aug 2021 22:45:01

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
User entered empty.	(b) (4), (b) (6)	17 Feb 2021 20:42:24

US3472020

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 11 Aug 2021 22:45:01

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
User entered empty.	(b) (4), (b) (6)	17 Feb 2021 20:42:24

US3472020

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 11 Aug 2021 22:45:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	7 Mar 2021 18:20:37
User entered empty.	(b) (4), (b) (6)	7 Feb 2021 20:42:24

US3472020

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 11 Aug 2021 22:45:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
User entered empty.	(b) (4), (b) (6)	17 Feb 2021 20:42:24

US3472020

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 11 Aug 2021 22:45:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
User entered '0'	(b) (4), (b) (6)	17 Feb 2021 20:42:24

US3472020

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 11 Aug 2021 22:45:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
User entered '0'		17 Feb 2021 20:42:24

US3472020

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 11 Aug 2021 22:45:01

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
User entered '0'	(b) (4), (b) (6)	17 Feb 2021 20:42:24

US3472020

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 11 Aug 2021 22:45:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	17 Feb 2021 20:42:24

US3472020

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 11 Aug 2021 22:45:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	17 Feb 2021 20:42:24

US3472020

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 11 Aug 2021 22:45:01

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	17 Feb 2021 20:42:24

US3472020

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 11 Aug 2021 22:45:01

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
User entered '0'	(b) (4), (b) (6)	17 Feb 2021 20:42:24

US3472020

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 11 Aug 2021 22:45:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 09:10:14
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'updated conmed log' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 14:10:10
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 10:11:06
User entered 'I'	(b) (4), (b) (6)	17 Feb 2021 20:42:24

US3472020

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 11 Aug 2021 22:45:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
User entered '0'		17 Feb 2021 20:42:24

US3472020

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 11 Aug 2021 22:45:01

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'		17 Feb 2021 20:42:24

US3472020

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 11 Aug 2021 22:45:01

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
User entered empty.	(b) (4), (b) (6)	17 Feb 2021 20:42:24

US3472020

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 11 Aug 2021 22:45:01

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
User entered empty.		17 Feb 2021 20:42:24

US3472020

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 11 Aug 2021 22:45:01

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:01
User entered '0'	System	17 Feb 2021 20:42:24

US3472020

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 11 Aug 2021 22:45:01

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:01
User entered '0'	System	17 Feb 2021 20:42:24

US3472020

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 11 Aug 2021 22:45:01

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:01

US3472020

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 11 Aug 2021 22:45:01

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:20:37
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Dental and oral soft tissue infections, PT: Parotitis, LLT: Parotitis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Feb 2021 17:56:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Feb 2021 17:56:55
Data point term sent to Coder	System	25 Feb 2021 17:56:41
User entered 'Parotitis'	(b) (4), (b) (6)	25 Feb 2021 17:55:42

US3472020

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 11 Aug 2021 22:45:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 16:04:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Feb 2021 17:55:42

US3472020

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 11 Aug 2021 22:45:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
User entered 'No (N)'		25 Feb 2021 17:55:42

US3472020

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 11 Aug 2021 22:45:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
User entered 'No (N)'		25 Feb 2021 17:55:42

US3472020

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 11 Aug 2021 22:45:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
User entered '15 Feb 2021'		25 Feb 2021 17:55:42

US3472020

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 11 Aug 2021 22:45:01

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:20:37
User entered empty.		25 Feb 2021 17:55:42

US3472020

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 11 Aug 2021 22:45:01

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Feb 2021 17:55:42

US3472020

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 11 Aug 2021 22:45:01

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
User entered 'Yes (Y)'	(b) (4)	25 Feb 2021 17:55:42

US3472020

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 11 Aug 2021 22:45:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
User entered empty.		25 Feb 2021 17:55:42

US3472020

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 11 Aug 2021 22:45:01

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
User entered empty.		25 Feb 2021 17:55:42

US3472020

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 11 Aug 2021 22:45:01

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Feb 2021 17:55:42

US3472020

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 11 Aug 2021 22:45:01

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	25 Feb 2021 17:55:42

US3472020

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 11 Aug 2021 22:45:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
User entered 'No (N)'		25 Feb 2021 17:55:42

US3472020

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 11 Aug 2021 22:45:01

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:20:37
User entered '0'		25 Feb 2021 17:55:42

US3472020

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 11 Aug 2021 22:45:01

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:20:37
User entered '0'		25 Feb 2021 17:55:42

US3472020

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 11 Aug 2021 22:45:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
User entered '0'		25 Feb 2021 17:55:42

US3472020

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 11 Aug 2021 22:45:01

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
User entered empty.		25 Feb 2021 17:55:42

US3472020

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 11 Aug 2021 22:45:01

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
User entered empty.		25 Feb 2021 17:55:42

US3472020

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 11 Aug 2021 22:45:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
User entered empty.	(b) (4)	25 Feb 2021 17:55:42

US3472020

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 11 Aug 2021 22:45:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
User entered empty.		25 Feb 2021 17:55:42

US3472020

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 11 Aug 2021 22:45:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
User entered '0'		25 Feb 2021 17:55:42

US3472020

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 11 Aug 2021 22:45:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
User entered '0'		25 Feb 2021 17:55:42

US3472020

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 11 Aug 2021 22:45:01

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
User entered '0'		25 Feb 2021 17:55:42

US3472020

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 11 Aug 2021 22:45:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4)	17 Mar 2021 18:20:37
User entered 'Related (RELATED)'	(b) (4), (b) (6)	25 Feb 2021 17:55:42

US3472020

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 11 Aug 2021 22:45:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:20:37
User entered 'Not Related (NOT RELATED)'		25 Feb 2021 17:55:42

US3472020

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 11 Aug 2021 22:45:01

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4)	17 Mar 2021 18:20:37
User closed query 'Per DM CLR: Action Taken with Investigational Product=Investigational Product Withdrawn. Ensure this is reflected in treatment discontinuation if applicable. Review and update. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 14:20:54
Query 'Per DM CLR: Action Taken with Investigational Product=Investigational Product Withdrawn. Ensure this is reflected in treatment discontinuation if applicable. Review and update. Else, clarify.' answered with 'dosing discontinuation form update' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 13:34:16
User opened query 'Per DM CLR: Action Taken with Investigational Product=Investigational Product Withdrawn. Ensure this is reflected in treatment discontinuation if applicable. Review and update. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	14 Mar 2021 18:46:02
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	(b) (4), (b) (6)	25 Feb 2021 17:55:42

US3472020

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 11 Aug 2021 22:45:01

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:20:37
User entered '0'		25 Feb 2021 17:55:42

US3472020

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 11 Aug 2021 22:45:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
User entered '1'		25 Feb 2021 17:55:42

US3472020

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 11 Aug 2021 22:45:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
User entered '0'		25 Feb 2021 17:55:42

US3472020

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 11 Aug 2021 22:45:01

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	25 Feb 2021 17:55:42

US3472020

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 11 Aug 2021 22:45:01

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
User entered empty.		25 Feb 2021 17:55:42

US3472020

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 11 Aug 2021 22:45:01

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:20:37
User entered empty.	(b) (4)	25 Feb 2021 17:55:42

US3472020

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 11 Aug 2021 22:45:01

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	25 Feb 2021 17:55:42

US3472020

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 11 Aug 2021 22:45:01

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Mar 2021 16:04:15
User entered '1'	System	25 Feb 2021 17:55:42

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:45:01

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:46:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:18:38
DataPoint Un-verified.		24 Dec 2020 04:16:50
DataPoint Verified.		16 Sep 2020 22:07:14
User entered 'Yes (Y)'		09 Sep 2020 03:31:13

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:45:01

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:07:59
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: ESCITALOPRAM OXALATE, PRODUCTSYNONYM: LEXAPRO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 03:36:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 03:36:31
Data point term sent to Coder User entered 'Lexapro'	System (b) (4), (b) (6)	09 Sep 2020 03:35:11 09 Sep 2020 03:34:38

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:45:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:07:59
User entered 'No (N)'	(b) (4), (b) (6)	09 Sep 2020 03:34:38

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:45:01

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:07:59
User entered 'Mood disorder'		09 Sep 2020 03:34:38

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:45:01

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:07:59
User entered '10'	(b) (4), (b) (6)	09 Sep 2020 03:34:38

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:45:01

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:07:59
User entered 'mg (mg)'		09 Sep 2020 03:34:38

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:45:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:07:59
User entered empty.	(b) (4), (b) (6)	09 Sep 2020 03:34:38

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:45:01

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:07:59
User entered 'once daily (QD)'		09 Sep 2020 03:34:38

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:45:01

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4)	16 Sep 2020 22:07:59
User entered empty.	(b) (4), (b) (6)	09 Sep 2020 03:34:38

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:45:01

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:07:59
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	09 Sep 2020 03:34:38

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:45:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:07:59
User entered empty.	(b) (4), (b) (6)	09 Sep 2020 03:34:38

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:45:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:07:59
User entered 'UN UNK 2017'		09 Sep 2020 03:34:38

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:45:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:07:59
User entered '0'		09 Sep 2020 03:34:38

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:45:01

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:07:59
User entered 'Yes (Y)'		09 Sep 2020 03:34:38

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:45:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:07:59
User entered empty.		09 Sep 2020 03:34:38

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:45:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:07:59
User entered 'No (N)'		09 Sep 2020 03:34:38

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:45:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 03:34:38

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:45:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 03:34:38

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:45:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Sep 2020 03:34:38

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:45:01

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:07:59
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM CITRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 12:20:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 12:20:51
Data point term sent to Coder	System	09 Sep 2020 03:37:12
User entered 'Mg citrate supplement'	(b) (4), (b) (6)	09 Sep 2020 03:37:05

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:45:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:18:45
User closed query 'Per CDM re-query: Response noted; The medications taken to promote current health status can be recorded as prophylactic. Please review the response and amend as appropriate else clarify.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 17:42:33
Query 'Per CDM re-query: Response noted; The medications taken to promote current health status can be recorded as prophylactic. Please review the response and amend as appropriate else clarify.' answered with 'updated to prophylactic' (Site from DM).	(b) (4), (b) (6)	29 Nov 2020 03:24:22
DataPoint Un-verified.	(b) (4), (b) (6)	29 Nov 2020 03:24:10
User entered 'Yes (Y)' reason for change: Per Query Resolution	(b) (4), (b) (6)	29 Nov 2020 03:24:10
User closed query 'Per DM CLR: Please verify if Prophylaxis should be changed to "Yes" as this medication is not given for treatment of a specific condition. Update the eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 11:34:43
User opened query 'Per CDM re-query: Response noted; The medications taken to promote current health status can be recorded as prophylactic. Please review the response and amend as appropriate else clarify.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 11:34:39
Query 'Per DM CLR: Please verify if Prophylaxis should be changed to "Yes" as this medication is not given for treatment of a specific condition. Update the eCRF as appropriate.' answered with 'Subject not taking to prevent disease, rather to promote current health status.' (Site from DM).	Jie Ho (b) (4)	12 Nov 2020 17:41:56
User opened query 'Per DM CLR: Please verify if Prophylaxis should be changed to "Yes" as this medication is not given for treatment of a specific condition. Update the eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 14:39:44
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:07:59

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:45:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	09 Sep 2020 03:37:05

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:45:01

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:07:59
User entered 'Nutritional support'		09 Sep 2020 03:37:05

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:45:01

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:07:59
User entered '200'		09 Sep 2020 03:37:05

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:45:01

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:07:59
User entered 'mg (mg)'		09 Sep 2020 03:37:05

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:45:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:07:59
User entered empty.		09 Sep 2020 03:37:05

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:45:01

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:07:59
User entered 'as needed (PRN)'		09 Sep 2020 03:37:05

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:45:01

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:07:59
User entered empty.		09 Sep 2020 03:37:05

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:45:01

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:07:59
User entered 'Oral (ORAL)'		09 Sep 2020 03:37:05

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:45:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:07:59
User entered empty.		09 Sep 2020 03:37:05

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:45:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:07:59
User entered '28 Aug 2020'		09 Sep 2020 03:37:05

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:45:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:07:59
User entered '0'		09 Sep 2020 03:37:05

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:45:01

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:07:59
User entered 'Yes (Y)'		09 Sep 2020 03:37:05

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:45:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:07:59
User entered empty.		09 Sep 2020 03:37:05

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:45:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:07:59
User entered 'No (N)'	(b) (4), (b) (6)	09 Sep 2020 03:37:05

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:45:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 03:37:05

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:45:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 03:37:05

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:45:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 03:37:05

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:45:01

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:07:59
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM GLYCINATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 12:23:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 12:23:39
Data point term sent to Coder	System	09 Sep 2020 03:39:13
User entered 'Mg glycinate supplement'	(b) (4), (b) (6)	09 Sep 2020 03:38:56

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:45:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4)	24 Dec 2020 04:18:45
User closed query 'Per CDM re-query: Response noted; The medications taken to promote current health status can be recorded as prophylactic. Please review the response and amend as appropriate else clarify.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 17:42:52
Query 'Per CDM re-query: Response noted; The medications taken to promote current health status can be recorded as prophylactic. Please review the response and amend as appropriate else clarify.' answered with 'updated to prophylactic' (Site from DM).	(b) (4), (b) (6)	29 Nov 2020 03:24:50
DataPoint Un-verified.	(b) (4), (b) (6)	29 Nov 2020 03:24:39
User entered 'Yes (Y)' reason for change: Per Query Resolution	(b) (4), (b) (6)	29 Nov 2020 03:24:39
User closed query 'Per DM CLR: Please verify if Prohyplaxis should be changed to "Yes" as this medication is not given for treatment of a specific condition. Update the eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 11:35:04
User opened query 'Per CDM re-query: Response noted; The medications taken to promote current health status can be recorded as prophylactic. Please review the response and amend as appropriate else clarify.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 11:35:03
Query 'Per DM CLR: Please verify if Prohyplaxis should be changed to "Yes" as this medication is not given for treatment of a specific condition. Update the eCRF as appropriate.' answered with 'Subject not taking to prevent disease, rather to promote current health status.' (Site from DM).	Jie Ho (b) (4)	12 Nov 2020 17:42:07
User opened query 'Per DM CLR: Please verify if Prohyplaxis should be changed to "Yes" as this medication is not given for treatment of a specific condition. Update the eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 14:39:59
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:07:59

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:45:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	09 Sep 2020 03:38:56

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:45:01

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:07:59
User entered 'Nutritional support'	(b) (4), (b) (6)	09 Sep 2020 03:38:56

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:45:01

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:07:59
User entered '200'		09 Sep 2020 03:38:56

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:45:01

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:07:59
User entered 'mg (mg)'		09 Sep 2020 03:38:56

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:45:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:07:59
User entered empty.	(b) (4), (b) (6)	09 Sep 2020 03:38:56

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:45:01

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:07:59
User entered 'as needed (PRN)'	(b) (4), (b) (6)	09 Sep 2020 03:38:56

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:45:01

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:07:59
User entered empty.		09 Sep 2020 03:38:56

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:45:01

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:07:59
User entered 'Oral (ORAL)'		09 Sep 2020 03:38:56

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:45:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:07:59
User entered empty.	(b) (4), (b) (6)	09 Sep 2020 03:38:56

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:45:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:07:59
User entered '28 Aug 2020'		09 Sep 2020 03:38:56

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:45:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:07:59
User entered '0'		09 Sep 2020 03:38:56

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:45:01

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:07:59
User entered 'Yes (Y)'		09 Sep 2020 03:38:56

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:45:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:07:59
User entered empty.		09 Sep 2020 03:38:56

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:45:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:07:59
User entered 'No (N)'		09 Sep 2020 03:38:56

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:45:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 03:38:56

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:45:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 03:38:56

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:45:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 03:38:56

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:45:01

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:18:45
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	01 Dec 2020 17:42:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	01 Dec 2020 17:42:58
Data point term sent to Coder	System	01 Dec 2020 17:41:52
User entered 'Influenza vaccination'	(b) (4), (b) (6)	01 Dec 2020 17:41:17

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:45:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:18:45
User entered 'Yes (Y)'		01 Dec 2020 17:41:17

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:45:01

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:18:45
User entered 'Influenza prophylaxis'	(b) (4), (b) (6)	01 Dec 2020 17:41:17

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:45:01

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:18:45
User entered '1'	(b) (4), (b) (6)	01 Dec 2020 17:41:17

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:45:01

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:18:45
User entered 'Other (OTHER)'	(b) (4), (b) (6)	01 Dec 2020 17:41:17

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:45:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:18:45
User entered 'Injection'		01 Dec 2020 17:41:17

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:45:01

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:18:45
User entered 'once (ONCE)'	(b) (4), (b) (6)	01 Dec 2020 17:41:17

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:45:01

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:18:45
User entered empty.		01 Dec 2020 17:41:17

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:45:01

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:18:45
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4)	01 Dec 2020 17:41:17

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:45:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:18:45
User entered empty.		01 Dec 2020 17:41:17

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:45:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4)	24 Dec 2020 04:18:45
User entered '10 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Dec 2020 17:41:36
User entered '01 Nov 2020'		01 Dec 2020 17:41:17

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:45:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:18:45
User entered '0'		01 Dec 2020 17:41:17

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:45:01

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:18:45
User entered 'No (N)'		01 Dec 2020 17:41:17

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:45:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4)	24 Dec 2020 04:18:45
User entered '10 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Dec 2020 17:41:36
User entered '01 Nov 2020'	(b) (4), (b) (6)	01 Dec 2020 17:41:17

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:45:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:18:45
User entered 'No (N)'		01 Dec 2020 17:41:17

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:45:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Dec 2020 17:41:17

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:45:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Dec 2020 17:41:17

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:45:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Dec 2020 17:41:17

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:45:01

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:18:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:44
Data point term sent to Coder	System	21 Dec 2020 20:19:55
User entered 'Acetaminophen'	(b) (4), (b) (6)	21 Dec 2020 20:19:01

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:45:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:18:45
User entered 'No (N)'		21 Dec 2020 20:19:01

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:45:01

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:18:45
User entered 'COVID-19'	(b) (4), (b) (6)	21 Dec 2020 20:19:01

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:45:01

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:18:45
User entered '650'	(b) (4)	21 Dec 2020 20:19:01

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:45:01

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:18:45
User entered 'mg (mg)'		21 Dec 2020 20:19:01

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:45:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:18:45
User entered empty.	(b) (4), (b) (6)	21 Dec 2020 20:19:01

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:45:01

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:18:45
User entered 'as needed (PRN)'	(b) (4)	21 Dec 2020 20:19:01

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:45:01

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:18:45
User entered empty.		21 Dec 2020 20:19:01

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:45:01

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:18:45
User entered 'Oral (ORAL)'		21 Dec 2020 20:19:01

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:45:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:18:45
User entered empty.	(b) (4), (b) (6)	21 Dec 2020 20:19:01

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:45:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:18:45
User entered '03 Dec 2020'		21 Dec 2020 20:19:01

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:45:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:18:45
User entered '0'	(b) (4), (b) (6)	21 Dec 2020 20:19:01

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:45:01

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:18:45
User entered 'No (N)'		21 Dec 2020 20:19:01

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:45:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:18:45
User entered '18 Dec 2020'		21 Dec 2020 20:19:01

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:45:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:18:45
User entered 'No (N)'		21 Dec 2020 20:19:01

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:45:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Dec 2020 20:19:01

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:45:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Dec 2020 20:19:01

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:45:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Dec 2020 20:19:01

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:45:01

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:21:12
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: ESCITALOPRAM OXALATE, PRODUCTSYNONYM: LEXAPRO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 19:50:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 19:50:30
Data point term sent to Coder User entered 'lexapro'	System (b) (4), (b) (6)	05 Jan 2021 19:49:25 05 Jan 2021 19:48:54

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:45:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered 'No (N)'		05 Jan 2021 19:48:54

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:45:01

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered 'Mood disorder'		05 Jan 2021 19:48:54

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:45:01

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered '4'		05 Jan 2021 19:48:54

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:45:01

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered 'mg (mg)'		05 Jan 2021 19:48:54

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:45:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered empty.		05 Jan 2021 19:48:54

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:45:01

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered 'once daily (QD)'		05 Jan 2021 19:48:54

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:45:01

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered empty.		05 Jan 2021 19:48:54

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:45:01

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered 'Oral (ORAL)'		05 Jan 2021 19:48:54

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:45:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered empty.	(b) (4)	05 Jan 2021 19:48:54

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:45:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:21:12
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening MOOD DISORDER should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 10:31:14
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening MOOD DISORDER should be recorded, and update con med indication or provide clarification. ' answered with 'condition did not worsen' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 18:13:04
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening MOOD DISORDER should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 12:29:34
User entered '2 Jan 2021'	(b) (4), (b) (6)	05 Jan 2021 19:48:54

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:45:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered '0'		05 Jan 2021 19:48:54

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:45:01

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered 'Yes (Y)'		05 Jan 2021 19:48:54

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:45:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered empty.	(b) (4), (b) (6)	05 Jan 2021 19:48:54

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:45:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:21:12
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Jan 2021 14:09:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Jan 2021 14:09:26
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Jan 2021 14:09:26
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Jan 2021 19:48:54
User entered empty.	(b) (4), (b) (6)	05 Jan 2021 19:48:54

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:45:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Jan 2021 19:48:54

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:45:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Jan 2021 19:48:54

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:45:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Jan 2021 19:48:54

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:45:01

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:21:12
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: NAPROXEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 18:50:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 18:50:06
Data point term sent to Coder	System	12 Feb 2021 18:49:17
User entered 'Naproxen'	(b) (4), (b) (6)	12 Feb 2021 18:49:03

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:45:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered 'No (N)'	(b) (4), (b) (6)	12 Feb 2021 18:49:03

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:45:01

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:21:12
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 10:00:52
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'Per protocol, indication is not reportable as an AE for part B.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 18:21:35
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 07:17:59
User entered 'Fever'	(b) (4), (b) (6)	12 Feb 2021 18:49:03

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:45:01

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered '1000'		12 Feb 2021 18:49:03

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:45:01

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered 'mg (mg)'	(b) (4), (b) (6)	12 Feb 2021 18:49:03

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:45:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered empty.		12 Feb 2021 18:49:03

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:45:01

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered 'as needed (PRN)'		12 Feb 2021 18:49:03

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:45:01

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered empty.		12 Feb 2021 18:49:03

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:45:01

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	12 Feb 2021 18:49:03

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:45:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered empty.		12 Feb 2021 18:49:03

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:45:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered '04 Feb 2021'	(b) (4)	12 Feb 2021 18:49:03

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:45:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered '0'		12 Feb 2021 18:49:03

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:45:01

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered 'No (N)'		12 Feb 2021 18:49:03

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:45:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered '06 Feb 2021'	(b) (4)	12 Feb 2021 18:49:03

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:45:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered 'No (N)'		12 Feb 2021 18:49:03

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:45:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Feb 2021 18:49:03

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:45:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Feb 2021 18:49:03

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:45:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Feb 2021 18:49:03

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:45:01

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:21:12
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 18:51:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 18:51:51
Data point term sent to Coder	System	12 Feb 2021 18:50:29
User entered 'Acetaminophen'	(b) (4), (b) (6)	12 Feb 2021 18:49:30

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:45:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered 'No (N)'	(b) (4), (b) (6)	12 Feb 2021 18:49:30

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:45:01

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:21:12
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 10:01:01
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'Per protocol, indication is not reportable as an AE for part B.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 18:21:53
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 07:18:07
User entered 'Fever'	(b) (4), (b) (6)	12 Feb 2021 18:49:30

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:45:01

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered '1000'		12 Feb 2021 18:49:30

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:45:01

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered 'mg (mg)'	(b) (4), (b) (6)	12 Feb 2021 18:49:30

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:45:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered empty.	(b) (4), (b) (6)	12 Feb 2021 18:49:30

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:45:01

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4)	17 Mar 2021 18:21:12
User entered 'as needed (PRN)'	(b) (4), (b) (6)	12 Feb 2021 18:49:30

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:45:01

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered empty.		12 Feb 2021 18:49:30

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:45:01

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered 'Oral (ORAL)'		12 Feb 2021 18:49:30

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:45:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered empty.	(b) (4), (b) (6)	12 Feb 2021 18:49:30

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:45:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered '04 Feb 2021'	(b) (4), (b) (6)	12 Feb 2021 18:49:30

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:45:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered '0'	(b) (4), (b) (6)	12 Feb 2021 18:49:30

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:45:01

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered 'No (N)'		12 Feb 2021 18:49:30

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:45:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered '06 Feb 2021'		12 Feb 2021 18:49:30

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:45:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered 'No (N)'		12 Feb 2021 18:49:30

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:45:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Feb 2021 18:49:30

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:45:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Feb 2021 18:49:30

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:45:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Feb 2021 18:49:30

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:45:01

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
User closed query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening) (for corticosteroids ≥ 20 mg/day of prednisone equivalent).' (Site from DM). Query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening) (for corticosteroids ≥ 20 mg/day of prednisone equivalent).' answered with 'updated - medication not taken for >14 days' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:22:00
User opened query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening) (for corticosteroids ≥ 20 mg/day of prednisone equivalent).' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 16:42:43
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	(b) (4), (b) (6) Coder Import (b) (4) (b) (4)	26 Mar 2021 15:22:52 24 Mar 2021 09:27:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 09:27:38
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:21:12
Data point term sent to Coder	System	25 Feb 2021 17:56:41
User entered 'Prednisone'	(b) (4), (b) (6)	25 Feb 2021 17:56:30

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:45:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered 'No (N)'		25 Feb 2021 17:56:30

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:45:01

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered 'Parotitis'	(b) (4), (b) (6)	25 Feb 2021 17:56:30

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:45:01

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered '40'		25 Feb 2021 17:56:30

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:45:01

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered 'mg (mg)'		25 Feb 2021 17:56:30

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:45:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered empty.	(b) (4)	25 Feb 2021 17:56:30

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:45:01

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered 'once daily (QD)'	(b) (4), (b) (6)	25 Feb 2021 17:56:30

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:45:01

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 17:56:30

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:45:01

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:21:12
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Feb 2021 17:56:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Feb 2021 17:56:38
User entered 'Oral (ORAL)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 17:56:38
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Feb 2021 17:56:30
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 17:56:30

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:45:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered empty.		25 Feb 2021 17:56:30

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:45:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 17 Mar 2021 18:21:12
User entered '25 Feb 2021'		25 Feb 2021 17:56:30

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:45:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered '0'		25 Feb 2021 17:56:30

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:45:01

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4)	08 Apr 2021 15:51:15
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 16:42:16
User entered 'No (N)' reason for change: New Information		06 Apr 2021 16:42:16
DataPoint Verified.		17 Mar 2021 18:21:12
User entered 'Yes (Y)'		25 Feb 2021 17:56:30

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:45:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4)	08 Apr 2021 15:51:15
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 16:42:16
User entered '03 Mar 2021' reason for change: New Information	(b) (4), (b) (6)	06 Apr 2021 16:42:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 17:56:30

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:45:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered 'No (N)'		25 Feb 2021 17:56:30

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:45:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Feb 2021 17:56:30

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:45:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Feb 2021 17:56:30

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:45:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Feb 2021 17:56:30

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:45:01

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4) (b) (4)	02 May 2021 18:58:11
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, PRODUCT: COUGH AND COLD PREPARATIONS - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 13:31:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 13:31:57
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:27:44
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;EPHEDRINE SULFATE;ETHANOL;PARACETAMOL, PRODUCTSYNONYM: NYQUIL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 11:35:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 11:35:49
Data point term sent to Coder	System	09 Apr 2021 17:00:37
User closed query 'CDM Coding : Per query response, please update the term as NYQUIL (NO FURTHER INFORMATION) in the drug name field. Please make changes appropriately. Thank you.' (Site from System).	System	09 Apr 2021 17:00:05
Query 'CDM Coding : Per query response, please update the term as NYQUIL (NO FURTHER INFORMATION) in the drug name field. Please make changes appropriately. Thank you.' answered with 'updated' (Site from System).	(b) (4), (b) (6)	09 Apr 2021 17:00:05
DataPoint Un-verified.		09 Apr 2021 16:59:48
Coding entries removed.		09 Apr 2021 16:59:48
User entered 'NYQUIL (no further information)' reason for change: Data Entry Error		09 Apr 2021 16:59:48

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:45:01

Name of Medication

Audit	User	Time (GMT)
User opened query 'CDM Coding : Per query response, please update the term as NYQUIL (NO FURTHER INFORMATION) in the drug name field. Please make changes appropriately. Thank you.' (Site from System).	Coder Import (b) (4)	09 Apr 2021 11:21:36
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;EPHEDRINE SULFATE;ETHANOL;PARACETAMOL, PRODUCTSYNONYM: NYQUIL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	07 Apr 2021 05:04:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	07 Apr 2021 05:04:32
Data point term sent to Coder	System	06 Apr 2021 16:44:07
User closed query 'For coding purposes, references indicate different formulations for NYQUIL Please provide generic ingredients, complete, accurate trade name and update the term with your response' (Site from System).	System	06 Apr 2021 16:43:58
Query 'For coding purposes, references indicate different formulations for NYQUIL Please provide generic ingredients, complete, accurate trade name and update the term with your response' answered with 'No further information regarding name available from participant' (Site from System).	(b) (4), (b) (6)	06 Apr 2021 16:43:58
User opened query 'For coding purposes, references indicate different formulations for NYQUIL Please provide generic ingredients, complete, accurate trade name and update the term with your response' (Site from System).	Coder Import (b) (4)	06 Apr 2021 14:56:55
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:21:12

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:45:01

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;EPHEDRINE SULFATE;ETHANOL;PARACETAMOL, PRODUCTSYNONYM: NYQUIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Mar 2021 14:07:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Mar 2021 14:07:49
Data point term sent to Coder	System	01 Mar 2021 14:07:33
User entered 'nyquil'	(b) (4), (b) (6)	01 Mar 2021 14:07:16

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:45:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered 'No (N)'		01 Mar 2021 14:07:16

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:45:01

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered 'sore throat'	(b) (4), (b) (6)	01 Mar 2021 14:07:16

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:45:01

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered '2'		01 Mar 2021 14:07:16

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:45:01

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4)	17 Mar 2021 18:21:12
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	01 Mar 2021 14:07:16

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:45:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered empty.		01 Mar 2021 14:07:16

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:45:01

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered 'once (ONCE)'		01 Mar 2021 14:07:16

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:45:01

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 14:07:16

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:45:01

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	01 Mar 2021 14:07:16

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:45:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered empty.		01 Mar 2021 14:07:16

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:45:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered '19 Jan 2021'		01 Mar 2021 14:07:16

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:45:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered '0'	(b) (4), (b) (6)	01 Mar 2021 14:07:16

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:45:01

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered 'No (N)'	(b) (4)	01 Mar 2021 14:07:16

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:45:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered '19 Jan 2021'		01 Mar 2021 14:07:16

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:45:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered 'No (N)'		01 Mar 2021 14:07:16

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:45:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 14:07:16

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:45:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 14:07:16

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:45:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 14:07:16

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:45:01

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, PRODUCT: COUGH AND COLD PREPARATIONS - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	20 Apr 2021 13:31:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 13:31:00
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:27:44
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;EPHEDRINE SULFATE;ETHANOL;PARACETAMOL, PRODUCTSYNONYM: NYQUIL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 11:35:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 11:35:49
Data point term sent to Coder	System	09 Apr 2021 17:07:57
User closed query 'CDM Coding : Per query response, please update the term as NYQUIL (NO FURTHER INFORMATION) in the drug name field. Please make changes appropriately. Thank you.' (Site from System).	System	09 Apr 2021 17:06:59
Query 'CDM Coding : Per query response, please update the term as NYQUIL (NO FURTHER INFORMATION) in the drug name field. Please make changes appropriately. Thank you.' answered with 'updated' (Site from System).	(b) (4), (b) (6)	09 Apr 2021 17:06:59
Data point term sent to Coder	System	09 Apr 2021 17:06:50
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 17:06:38
Coding entries removed.		09 Apr 2021 17:06:38
User entered 'NYQUIL (no further information)' reason for change: Data Entry Error		09 Apr 2021 17:06:38

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US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:45:01

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'CDM Coding : Per query response, please update the term as NYQUIL (NO FURTHER INFORMATION) in the drug name field. Please make changes appropriately. Thank you.' (Site from System).	Coder Import (b) (4)	09 Apr 2021 11:20:31
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;EPHEDRINE SULFATE;ETHANOL;PARACETAMOL, PRODUCTSYNONYM: NYQUIL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	07 Apr 2021 05:05:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	07 Apr 2021 05:05:34
Data point term sent to Coder	System	06 Apr 2021 16:44:06
User closed query 'For coding purposes, references indicate different formulations for NYQUIL Please provide generic ingredients, complete, accurate trade name and update the term with your response' (Site from System).	System	06 Apr 2021 16:44:03
Query 'For coding purposes, references indicate different formulations for NYQUIL Please provide generic ingredients, complete, accurate trade name and update the term with your response' answered with 'No further information regarding name available from participant' (Site from System).	(b) (4), (b) (6)	06 Apr 2021 16:44:03
User opened query 'For coding purposes, references indicate different formulations for NYQUIL Please provide generic ingredients, complete, accurate trade name and update the term with your response' (Site from System).	Coder Import (b) (4)	06 Apr 2021 15:02:44
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:21:12

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:45:01

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;EPHEDRINE SULFATE;ETHANOL;PARACETAMOL, PRODUCTSYNONYM: NYQUIL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	01 Mar 2021 14:11:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	01 Mar 2021 14:11:57
Data point term sent to Coder	System	01 Mar 2021 14:10:34
User entered 'nyquil'	(b) (4), (b) (6)	01 Mar 2021 14:09:45

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:45:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered 'No (N)'		01 Mar 2021 14:09:45

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:45:01

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:21:12
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if applicable. Else, clarify ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 10:53:27
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if applicable. Else, clarify ' answered with 'Per protocol, this indication is not reportable as an AE.' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 13:31:02
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if applicable. Else, clarify ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 04:27:55
User entered 'malaise'	(b) (4), (b) (6)	01 Mar 2021 14:09:45

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:45:01

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered '2'		01 Mar 2021 14:09:45

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:45:01

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered 'tablet (TABLET)'		01 Mar 2021 14:09:45

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:45:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered empty.		01 Mar 2021 14:09:45

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:45:01

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered 'once (ONCE)'	(b) (4)	01 Mar 2021 14:09:45

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:45:01

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered empty.	(b) (4)	01 Mar 2021 14:09:45

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:45:01

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered 'Oral (ORAL)'		01 Mar 2021 14:09:45

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:45:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered empty.		01 Mar 2021 14:09:45

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:45:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered '04 Feb 2021'		01 Mar 2021 14:09:45

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:45:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered '0'		01 Mar 2021 14:09:45

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:45:01

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered 'No (N)'		01 Mar 2021 14:09:45

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:45:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered '04 Feb 2021'	(b) (4), (b) (6)	01 Mar 2021 14:09:45

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:45:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered 'No (N)'		01 Mar 2021 14:09:45

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:45:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 14:09:45

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:45:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 14:09:45

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:45:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 14:09:45

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:45:01

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:21:12
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 16:07:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 16:07:53
Data point term sent to Coder	System	05 Mar 2021 16:07:29
User entered 'Acetaminophen'	(b) (4), (b) (6)	05 Mar 2021 16:07:00

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:45:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered 'No (N)'	(b) (4), (b) (6)	05 Mar 2021 16:07:00

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:45:01

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4)	17 Mar 2021 18:21:12
User entered 'Parotitis'	(b) (4), (b) (6)	05 Mar 2021 16:07:00

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:45:01

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered '1000'		05 Mar 2021 16:07:00

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:45:01

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered 'mg (mg)'		05 Mar 2021 16:07:00

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:45:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered empty.		05 Mar 2021 16:07:00

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:45:01

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered 'once (ONCE)'	(b) (4), (b) (6)	05 Mar 2021 16:07:00

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:45:01

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered empty.		05 Mar 2021 16:07:00

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:45:01

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered 'Oral (ORAL)'		05 Mar 2021 16:07:00

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:45:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered empty.		05 Mar 2021 16:07:00

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:45:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered '25 Feb 2021'		05 Mar 2021 16:07:00

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:45:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered '0'		05 Mar 2021 16:07:00

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:45:01

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered 'No (N)'		05 Mar 2021 16:07:00

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:45:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered '25 Feb 2021'		05 Mar 2021 16:07:00

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:45:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:21:12
User entered 'No (N)'		05 Mar 2021 16:07:00

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:45:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Mar 2021 16:07:00

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:45:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Mar 2021 16:07:00

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:45:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Mar 2021 16:07:00

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:45:01

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:51:15
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 12:30:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 12:30:57
Data point term sent to Coder	System	05 Apr 2021 20:18:44
User entered 'Meloxicam'	(b) (4), (b) (6)	05 Apr 2021 20:18:32

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:45:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:51:15
User entered 'No (N)'		05 Apr 2021 20:18:32

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:45:01

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:51:15
User entered 'Parotitis'		05 Apr 2021 20:18:32

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:45:01

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:15
User entered '15'	(b) (4), (b) (6)	05 Apr 2021 20:18:32

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:45:01

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:51:15
User entered 'mg (mg)'		05 Apr 2021 20:18:32

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:45:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:51:15
User entered empty.		05 Apr 2021 20:18:32

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:45:01

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:15
User entered 'once daily (QD)'	(b) (4), (b) (6)	05 Apr 2021 20:18:32

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:45:01

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4)	08 Apr 2021 15:51:15
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 20:18:32

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:45:01

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4)	08 Apr 2021 15:51:15
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	05 Apr 2021 20:18:32

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:45:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:51:15
User entered empty.		05 Apr 2021 20:18:32

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:45:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:51:15
User entered '16 Mar 2021'		05 Apr 2021 20:18:32

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:45:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:51:15
User entered '0'		05 Apr 2021 20:18:32

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:45:01

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:51:15
User entered 'Yes (Y)'		05 Apr 2021 20:18:32

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:45:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:51:15
User entered empty.		05 Apr 2021 20:18:32

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:45:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:51:15
User entered 'No (N)'		05 Apr 2021 20:18:32

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:45:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 20:18:32

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:45:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 20:18:32

US3472020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:45:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Apr 2021 20:18:32

US3472020

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:45:01

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:15
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:56:31

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:01

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:18:18
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 16:16:28
User entered 'USA-US122-2020-MRNA-1273-P301000005'	System	11 Dec 2020 16:15:42

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:01

Serious

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:18:18
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 16:16:28
User entered 'No (N)'	System	11 Dec 2020 16:15:42

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:01

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:18:18
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 16:16:28
User entered 'No (N)'	System	11 Dec 2020 16:15:42

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:01

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:18:18
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 16:16:28
User entered 'No (N)'	System	11 Dec 2020 16:15:42

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:18:18
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 16:16:28
User entered 'No (N)'	System	11 Dec 2020 16:15:42

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:18:18
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 16:16:28
User entered 'No (N)'	System	11 Dec 2020 16:15:42

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:18:18
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 16:16:28
User entered 'No (N)'	System	11 Dec 2020 16:15:42

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:01

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:18:18
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 16:16:28
User entered 'No (N)'	System	11 Dec 2020 16:15:42

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:01

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 15:19:41
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:18:18
User entered 'US'	System	11 Dec 2020 16:17:27

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:01

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	05 Jan 2021 15:19:52
User entered '3'	System	23 Dec 2020 20:36:47
User entered '2'	System	22 Dec 2020 21:03:23
User entered '1'	System	11 Dec 2020 16:17:27

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:01

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:18:18
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 16:16:28
User entered 'USA-US122-2020-MRNA-1273-P301000005'	System	11 Dec 2020 16:15:42

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:01

Serious

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:18:18
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 16:16:28
User entered 'No (N)'	System	11 Dec 2020 16:15:42

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:01

Death

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:18:18
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 16:16:28
User entered 'No (N)'	System	11 Dec 2020 16:15:42

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:01

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:18:18
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 16:16:28
User entered 'No (N)'	System	11 Dec 2020 16:15:42

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:18:18
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 16:16:28
User entered 'No (N)'	System	11 Dec 2020 16:15:42

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:18:18
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 16:16:28
User entered 'No (N)'	System	11 Dec 2020 16:15:42

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:18:18
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 16:16:28
User entered 'No (N)'	System	11 Dec 2020 16:15:42

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:01

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:18:18
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 16:16:28
User entered 'No (N)'	System	11 Dec 2020 16:15:42

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:01

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 15:19:41
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:18:18
User entered 'US'	System	11 Dec 2020 16:17:27

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:01

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	05 Jan 2021 15:19:52
User entered '3'	System	23 Dec 2020 20:36:47
User entered '2'	System	22 Dec 2020 21:03:23
User entered '1'	System	11 Dec 2020 16:17:27

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:45:01

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:18:18
User entered '11/Dec/2020 16:17'	System	11 Dec 2020 16:17:27

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:45:01

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)	29 Mar 2021 15:38:16
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 15:19:41
DataPoint Verified.		24 Dec 2020 04:18:18
User entered '1'		11 Dec 2020 16:17:27

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:01

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:18:18
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 16:16:28
User entered 'USA-US122-2020-MRNA-1273-P301000005'	System	11 Dec 2020 16:15:42

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:01

Serious

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:18:18
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 16:16:28
User entered 'No (N)'	System	11 Dec 2020 16:15:42

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:01

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:18:18
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 16:16:28
User entered 'No (N)'	System	11 Dec 2020 16:15:42

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:01

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:18:18
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 16:16:28
User entered 'No (N)'	System	11 Dec 2020 16:15:42

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:18:18
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 16:16:28
User entered 'No (N)'	System	11 Dec 2020 16:15:42

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:18:18
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 16:16:28
User entered 'No (N)'	System	11 Dec 2020 16:15:42

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:18:18
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 16:16:28
User entered 'No (N)'	System	11 Dec 2020 16:15:42

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:01

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:18:18
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 16:16:28
User entered 'No (N)'	System	11 Dec 2020 16:15:42

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:01

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 15:19:41
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:18:18
User entered 'US'	System	11 Dec 2020 16:17:27

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:01

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	05 Jan 2021 15:19:52
User entered '3'	System	23 Dec 2020 20:36:47
User entered '2'	System	22 Dec 2020 21:03:23
User entered '1'	System	11 Dec 2020 16:17:27

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:45:01

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:18:18
User entered '22/Dec/2020 16:03'	System	22 Dec 2020 21:03:23

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:45:01

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)	29 Mar 2021 15:38:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 15:19:41
DataPoint Verified.		24 Dec 2020 04:18:18
User entered '1'		22 Dec 2020 21:03:23

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:01

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:18:18
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 16:16:28
User entered 'USA-US122-2020-MRNA-1273-P301000005'	System	11 Dec 2020 16:15:42

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:01

Serious

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:18:18
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 16:16:28
User entered 'No (N)'	System	11 Dec 2020 16:15:42

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:01

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:18:18
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 16:16:28
User entered 'No (N)'	System	11 Dec 2020 16:15:42

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:01

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:18:18
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 16:16:28
User entered 'No (N)'	System	11 Dec 2020 16:15:42

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:18:18
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 16:16:28
User entered 'No (N)'	System	11 Dec 2020 16:15:42

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:18:18
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 16:16:28
User entered 'No (N)'	System	11 Dec 2020 16:15:42

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:18:18
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 16:16:28
User entered 'No (N)'	System	11 Dec 2020 16:15:42

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:01

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:18:18
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 16:16:28
User entered 'No (N)'	System	11 Dec 2020 16:15:42

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:01

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 15:19:41
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:18:18
User entered 'US'	System	11 Dec 2020 16:17:27

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:01

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	05 Jan 2021 15:19:52
User entered '3'	System	23 Dec 2020 20:36:47
User entered '2'	System	22 Dec 2020 21:03:23
User entered '1'	System	11 Dec 2020 16:17:27

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:45:01

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:18:18
User entered '23/Dec/2020 15:36'	System	23 Dec 2020 20:36:47

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:45:01

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)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:18:18
Reviewed for Safety.		23 Dec 2020 20:36:54
User entered '1'		23 Dec 2020 20:36:47

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:01

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:18:18
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 16:16:28
User entered 'USA-US122-2020-MRNA-1273-P301000005'	System	11 Dec 2020 16:15:42

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:01

Serious

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:18:18
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 16:16:28
User entered 'No (N)'	System	11 Dec 2020 16:15:42

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:01

Death

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:18:18
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 16:16:28
User entered 'No (N)'	System	11 Dec 2020 16:15:42

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:01

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:18:18
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 16:16:28
User entered 'No (N)'	System	11 Dec 2020 16:15:42

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:18:18
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 16:16:28
User entered 'No (N)'	System	11 Dec 2020 16:15:42

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:18:18
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 16:16:28
User entered 'No (N)'	System	11 Dec 2020 16:15:42

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:18:18
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 16:16:28
User entered 'No (N)'	System	11 Dec 2020 16:15:42

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:01

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:18:18
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 16:16:28
User entered 'No (N)'	System	11 Dec 2020 16:15:42

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:01

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 15:19:41
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 04:18:18
User entered 'US'	System	11 Dec 2020 16:17:27

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:01

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	05 Jan 2021 15:19:52
User entered '3'	System	23 Dec 2020 20:36:47
User entered '2'	System	22 Dec 2020 21:03:23
User entered '1'	System	11 Dec 2020 16:17:27

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 11 Aug 2021 22:45:01

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:15
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered '05/Jan/2021 10:19'	(b) (4) System	05 Jan 2021 15:19:52

US3472020

Folder: SAE USA-US122-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 11 Aug 2021 22:45:01

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)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:15
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:38:16
User entered '1'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 15:19:52