

US3482286 (Prod: Hope Clinic of The Emory Vaccine Center)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:51:52

All time stamps listed in this document are displayed in GMT

US3482286

Form: Participant Creation

Data signed: (b) (4) 01 Apr 2021 23:34:40

Generated On: 09 Jun 2021 17:51:52

Participant ID

US3482286

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

US3482286

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 15:39:16

Generated On: 09 Jun 2021 17:51:52

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

Visit date (dd MMM yyyy)	13 OCT 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SCRN
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US3482286

Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 15:39:16

Generated On: 09 Jun 2021 17:51:52

Date of Birth (MMM yyyy)	(b) (6) 1968
Age	52
Age Units	YEARS
Age (Derived)	52
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	True
Asian	True
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

US3482286

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 15:39:16

Generated On: 09 Jun 2021 17:51:52

Date of Informed Consent (<i>dd MMM yyyy</i>)	13 OCT 2020
Month and Year of Informed Consent (derived)	OCT 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input checked="" type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 15:39:16

Generated On: 09 Jun 2021 17:51:52

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 15:39:16

Generated On: 09 Jun 2021 17:51:52

Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 13 Feb 2021 15:39:16

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Condition	ELEVATED BLOOD PRESSURE
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 15:39:16

Generated On: 09 Jun 2021 17:51:52

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	13 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	09:15 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 09:15
Height (<i>xxx.x</i>)	71 in
Weight (<i>xxx.x</i>)	186 lb
BMI (<i>xxx.x</i>)	25.99598 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) 13 Feb 2021 15:39:16

Generated On: 09 Jun 2021 17:51:52

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 OCT 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 15:39:16

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

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) 13 Feb 2021 15:39:16

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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	True
Specify	RESIDES IN A COMMUNITY WITH ONGOING PERSON TO PERSON TO TRANSMISSION

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 15:39:16

Generated On: 09 Jun 2021 17:51:52

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

Visit date (dd MMM yyyy)	13 OCT 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT1
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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 15:39:16

Generated On: 09 Jun 2021 17:51:52

What was the date of randomization? (dd MMM yyyy) 13 OCT 2020

What was the participant's randomization number? 113373

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) 13 Feb 2021 15:39:16

Generated On: 09 Jun 2021 17:51:52

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) 13 Feb 2021 15:39:16

Generated On: 09 Jun 2021 17:51:52

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 OCT 2020
Time of assessment (00:00-23:59)	09:15 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 09:15
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	98 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 15:39:16

Generated On: 09 Jun 2021 17:51:52

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	13 OCT 2020
Time of assessment (00:00-23:59)	11:15 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 11:15
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	151 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	98 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 15:39:16

Generated On: 09 Jun 2021 17:51:52

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 OCT 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 15:39:16

Generated On: 09 Jun 2021 17:51:52

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) 13 OCT 2020

What was the treatment time? (00:00-23:59) 10:40 (24 HR)

Treatment Date and Time (derived) 13 OCT 2020 10:40

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) 13 Feb 2021 15:39:16

Generated On: 09 Jun 2021 17:51:52

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

13 OCT 2020

Collection time (00:00-23:59)

10:10 (24 HR)

Collection date and time (derived)

13 OCT 2020 10:10

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 15:39:16

Generated On: 09 Jun 2021 17:51:52

Collection date (dd MMM yyyy)			13 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:15	13 OCT 2020 10:15
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:39:16

Generated On: 09 Jun 2021 17:51:52

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: 09 Jun 2021 17:51:52

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 OCT 2020 11:27

PC Open Date & Time

13 OCT 2020 11:00

PC Close Date & Time

13 OCT 2020 13:30

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:51:52

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 97.2 °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	13 OCT 2020 16:02
PC Open Date & Time	13 OCT 2020 14:25
PC Close Date & Time	14 OCT 2020 11:59

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 OCT 2020 08:02

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 OCT 2020 12:00

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 OCT 2020 12:55

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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

18 OCT 2020 00:54

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 OCT 2020 12:19

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 OCT 2020 08:54

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:51:52

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

13 OCT 2020 11:27

PC Open Date & Time

13 OCT 2020 11:00

PC Close Date & Time

13 OCT 2020 13:30

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:51:52

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

13 OCT 2020 16:02

PC Open Date & Time

13 OCT 2020 14:25

PC Close Date & Time

14 OCT 2020 11:59

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 OCT 2020 08:02

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 OCT 2020 12:00

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 OCT 2020 12:55

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 OCT 2020 00:55

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 OCT 2020 12:20

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 OCT 2020 08:54

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:51:52

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 ☐

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:51:52

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

No ☒

Yes ☐

PC Time stamp	13 OCT 2020 11:28
PC Open Date & Time	13 OCT 2020 11:00
PC Close Date & Time	13 OCT 2020 13:30

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:51:52

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 ☐

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:51:52

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

No ☒

Yes ☐

PC Time stamp	13 OCT 2020 16:02
PC Open Date & Time	13 OCT 2020 14:25
PC Close Date & Time	14 OCT 2020 11:59

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:51:52

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 ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:51:52

Yes <input type="checkbox"/>	
PC Time stamp	15 OCT 2020 08:02
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:51:52

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 ☒

PRODUCTION RELEASE (v12.003

44 of 2466

EAB) (1725)

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:51:52

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

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:51:52

Yes <input type="checkbox"/>	
PC Time stamp	16 OCT 2020 12:56
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

48 of 2466

EAB) (1725)

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:51:52

Yes <input type="checkbox"/>	
PC Time stamp	18 OCT 2020 00:55
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

50 of 2466

EAB) (1725)

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:51:52

Yes <input type="checkbox"/>	
PC Time stamp	18 OCT 2020 12:20
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

52 of 2466

EAB) (1725)

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:51:52

Yes <input type="checkbox"/>	
PC Time stamp	20 OCT 2020 08:54
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3482286

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 15:39:16

Generated On: 09 Jun 2021 17:51:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482286

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:39:16

Generated On: 09 Jun 2021 17:51:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482286

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 15:39:16

Generated On: 09 Jun 2021 17:51:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482286

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:39:16

Generated On: 09 Jun 2021 17:51:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482286

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 15:39:16

Generated On: 09 Jun 2021 17:51:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482286

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:39:16

Generated On: 09 Jun 2021 17:51:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482286

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 15:39:17

Generated On: 09 Jun 2021 17:51:52

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

Visit date (dd MMM yyyy)	12 NOV 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT2
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US3482286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 15:39:17

Generated On: 09 Jun 2021 17:51:52

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)	12 NOV 2020
Time of assessment (00:00-23:59)	08:15 (24 HR)
Vital Signs Date and Time (derived)	12 NOV 2020 08:15
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	141 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG

US3482286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 15:39:17

Generated On: 09 Jun 2021 17:51:52

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)	12 NOV 2020
Time of assessment (00:00-23:59)	09:30 (24 HR)
Vital Signs Date and Time (derived)	12 NOV 2020 09:30
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)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	93 mmHg
Diastolic Blood Pressure units	MMHG

US3482286

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 15:39:17

Generated On: 09 Jun 2021 17:51:52

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 NOV 2020

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

US3482286

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 15:39:17

Generated On: 09 Jun 2021 17:51:52

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) 12 NOV 2020

What was the treatment time? (00:00-23:59) 08:59 (24 HR)

Treatment Date and Time (derived) 12 NOV 2020 08:59

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

US3482286

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 15:39:17

Generated On: 09 Jun 2021 17:51:52

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 NOV 2020

Collection time (00:00-23:59)

8:20 (24 HR)

Collection date and time (derived)

12 NOV 2020 8:20

US3482286

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 15:39:16

Generated On: 09 Jun 2021 17:51:52

Collection date (dd MMM yyyy)			12 NOV 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:23	12 NOV 2020 08:23
Nasopharyngeal Swab 2	No		

US3482286

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:39:17

Generated On: 09 Jun 2021 17:51:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:51:52

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

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 NOV 2020 09:25

PC Open Date & Time

12 NOV 2020 09:19

PC Close Date & Time

12 NOV 2020 11:49

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.6 °F

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

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

PC Time Stamp	12 NOV 2020 13:09
PC Open Date & Time	12 NOV 2020 12:44
PC Close Date & Time	13 NOV 2020 11:59

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 NOV 2020 07:26

PC Open Date & Time

13 NOV 2020 12:00

PC Close Date & Time

14 NOV 2020 11:59

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

15 NOV 2020 09:09

PC Open Date & Time

14 NOV 2020 12:00

PC Close Date & Time

15 NOV 2020 11:59

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

15 NOV 2020 12:32

PC Open Date & Time

15 NOV 2020 12:00

PC Close Date & Time

16 NOV 2020 11:59

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:51:52

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 ☒

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

Yes ☐

No ☒

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

PC Time Stamp 16 NOV 2020 12:00

PC Open Date & Time 16 NOV 2020 12:00

PC Close Date & Time 17 NOV 2020 11:59

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 NOV 2020 15:38

PC Open Date & Time

17 NOV 2020 12:00

PC Close Date & Time

18 NOV 2020 11:59

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 NOV 2020 15:50

PC Open Date & Time

18 NOV 2020 12:00

PC Close Date & Time

19 NOV 2020 11:59

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:51:52

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

12 NOV 2020 09:32

PC Open Date & Time

12 NOV 2020 09:19

PC Close Date & Time

12 NOV 2020 11:49

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:51:52

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

12 NOV 2020 13:09

PC Open Date & Time

12 NOV 2020 12:44

PC Close Date & Time

13 NOV 2020 11:59

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 NOV 2020 07:27

PC Open Date & Time

13 NOV 2020 12:00

PC Close Date & Time

14 NOV 2020 11:59

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 NOV 2020 09:10

PC Open Date & Time

14 NOV 2020 12:00

PC Close Date & Time

15 NOV 2020 11:59

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 NOV 2020 12:32

PC Open Date & Time

15 NOV 2020 12:00

PC Close Date & Time

16 NOV 2020 11:59

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 NOV 2020 12:00

PC Open Date & Time

16 NOV 2020 12:00

PC Close Date & Time

17 NOV 2020 11:59

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 NOV 2020 15:39

PC Open Date & Time

17 NOV 2020 12:00

PC Close Date & Time

18 NOV 2020 11:59

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 NOV 2020 15:51

PC Open Date & Time

18 NOV 2020 12:00

PC Close Date & Time

19 NOV 2020 11:59

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:51:52

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 ☐

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:51:52

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

No ☒

Yes ☐

PC Time stamp	12 NOV 2020 09:33
PC Open Date & Time	12 NOV 2020 09:19
PC Close Date & Time	12 NOV 2020 11:49

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:51:52

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 ☐

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:51:52

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

No ☒

Yes ☐

PC Time stamp	12 NOV 2020 13:09
PC Open Date & Time	12 NOV 2020 12:44
PC Close Date & Time	13 NOV 2020 11:59

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:51:52

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 ☒

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:51:52

Yes <input type="checkbox"/>	
PC Time stamp	14 NOV 2020 07:27
PC Open Date & Time	13 NOV 2020 12:00
PC Close Date & Time	14 NOV 2020 11:59

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:51:52

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 ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:51:52

Yes <input type="checkbox"/>	
PC Time stamp	15 NOV 2020 09:10
PC Open Date & Time	14 NOV 2020 12:00
PC Close Date & Time	15 NOV 2020 11:59

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:51:52

Yes <input type="checkbox"/>	
PC Time stamp	15 NOV 2020 12:32
PC Open Date & Time	15 NOV 2020 12:00
PC Close Date & Time	16 NOV 2020 11:59

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:51:52

Yes <input type="checkbox"/>	
PC Time stamp	16 NOV 2020 12:01
PC Open Date & Time	16 NOV 2020 12:00
PC Close Date & Time	17 NOV 2020 11:59

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:51:52

Yes <input type="checkbox"/>	
PC Time stamp	17 NOV 2020 15:39
PC Open Date & Time	17 NOV 2020 12:00
PC Close Date & Time	18 NOV 2020 11:59

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:51:52

Yes <input type="checkbox"/>	
PC Time stamp	18 NOV 2020 15:51
PC Open Date & Time	18 NOV 2020 12:00
PC Close Date & Time	19 NOV 2020 11:59

US3482286

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 15:39:16

Generated On: 09 Jun 2021 17:51:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482286

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:39:16

Generated On: 09 Jun 2021 17:51:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482286

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 15:39:16

Generated On: 09 Jun 2021 17:51:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482286

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:39:16

Generated On: 09 Jun 2021 17:51:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482286

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 15:39:16

Generated On: 09 Jun 2021 17:51:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482286

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:39:16

Generated On: 09 Jun 2021 17:51:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482286

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 15:39:17

Generated On: 09 Jun 2021 17:51:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3482286

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 15:39:17

Generated On: 09 Jun 2021 17:51:52

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3482286

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 15:39:17

Generated On: 09 Jun 2021 17:51:52

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.

US3482286

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 15:39:17

Generated On: 09 Jun 2021 17:51:52

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

10 DEC 2020

Collection time (00:00-23:59)

09:20 (24 HR)

Collection date and time (derived)

10 DEC 2020 09:20

US3482286

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:39:17

Generated On: 09 Jun 2021 17:51:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 DEC 2020 08:55:08
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 DEC 2020 00:02:24
Patient Cloud Open Date & Time	17 DEC 2020 00:01
Patient Cloud Close Date & Time	21 DEC 2020 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 DEC 2020 12:29:56
Patient Cloud Open Date & Time	24 DEC 2020 00:01
Patient Cloud Close Date & Time	28 DEC 2020 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 JAN 2021 15:49:55
Patient Cloud Open Date & Time	31 DEC 2020 00:01
Patient Cloud Close Date & Time	04 JAN 2021 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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	True
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	False
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	07 JAN 2021 08:16:33
Patient Cloud Open Date & Time	07 JAN 2021 00:01
Patient Cloud Close Date & Time	11 JAN 2021 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 JAN 2021 12:26:19
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 JAN 2021 12:10:31

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 JAN 2021 13:45:08

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 FEB 2021 12:07:45

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	11 FEB 2021 12:40:20
Patient Cloud Open Date & Time	11 FEB 2021 00:01
Patient Cloud Close Date & Time	15 FEB 2021 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 FEB 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 FEB 2021 17:00:38
Patient Cloud Open Date & Time	25 FEB 2021 00:01
Patient Cloud Close Date & Time	01 MAR 2021 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 MAR 2021 06:56:01
Patient Cloud Open Date & Time	04 MAR 2021 00:01
Patient Cloud Close Date & Time	08 MAR 2021 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 MAR 2021 12:10:43

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 MAR 2021 09:51:34

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 MAR 2021 00:06:51

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 APR 2021 17:59:27

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 APR 2021 12:58:17
Patient Cloud Open Date & Time	08 APR 2021 00:01
Patient Cloud Close Date & Time	12 APR 2021 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 APR 2021 07:30:55
Patient Cloud Open Date & Time	15 APR 2021 00:01
Patient Cloud Close Date & Time	19 APR 2021 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

22 APR 2021 00:08:26

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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	29 APR 2021 00:02:21
Patient Cloud Open Date & Time	29 APR 2021 00:01
Patient Cloud Close Date & Time	03 MAY 2021 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

DAY 208

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

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

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 MAY 2021 00:01
Patient Cloud Close Date & Time	31 MAY 2021 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 JUN 2021 00:01
Patient Cloud Close Date & Time	14 JUN 2021 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

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 ☐

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 JUL 2021 00:01
Patient Cloud Close Date & Time	19 JUL 2021 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 JUL 2021 00:01
Patient Cloud Close Date & Time	26 JUL 2021 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

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

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

[Patient Cloud Open Date & Time](#)

12 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 AUG 2021 00:01
Patient Cloud Close Date & Time	30 AUG 2021 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

[Patient Cloud Open Date & Time](#)

09 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

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

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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 ☐

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 OCT 2021 00:01
Patient Cloud Close Date & Time	18 OCT 2021 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 OCT 2021 00:01
Patient Cloud Close Date & Time	25 OCT 2021 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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 ☐

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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 ☐

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

[Patient Cloud Open Date & Time](#)

11 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 NOV 2021 00:01
Patient Cloud Close Date & Time	29 NOV 2021 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

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 ☐

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

[Patient Cloud Open Date & Time](#)

02 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

[Patient Cloud Open Date & Time](#)

09 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 DEC 2021 00:01
Patient Cloud Close Date & Time	20 DEC 2021 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

Patient Cloud Open Date & Time	23 DEC 2021 00:01
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Patient Cloud Close Date & Time	27 DEC 2021 23:59
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US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

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

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	06 JAN 2022 00:01
Patient Cloud Close Date & Time	10 JAN 2022 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

[Patient Cloud Open Date & Time](#)

13 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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 ☐

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

[Patient Cloud Open Date & Time](#)

27 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

[Patient Cloud Open Date & Time](#)

17 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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 ☐

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

[Patient Cloud Open Date & Time](#)

10 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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 ☐

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 MAR 2022 00:01
Patient Cloud Close Date & Time	21 MAR 2022 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

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

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

[Patient Cloud Open Date & Time](#)

14 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

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

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

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

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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 ☐

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 JUN 2022 00:01
Patient Cloud Close Date & Time	27 JUN 2022 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	30 JUN 2022 00:01
Patient Cloud Close Date & Time	04 JUL 2022 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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 ☐

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

[Patient Cloud Open Date & Time](#)

21 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2022 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

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

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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 ☐

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT	DAY 677
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

Patient Cloud Open Date & Time	25 AUG 2022 00:01
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Patient Cloud Close Date & Time	29 AUG 2022 23:59
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US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

[Patient Cloud Open Date & Time](#)

01 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

[Patient Cloud Open Date & Time](#)

22 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	06 OCT 2022 00:01
Patient Cloud Close Date & Time	10 OCT 2022 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

Patient Cloud Open Date & Time	20 OCT 2022 00:01
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Patient Cloud Close Date & Time	24 OCT 2022 23:59
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US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

[Patient Cloud Open Date & Time](#)

27 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2022 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2022 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

14 NOV 2022 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

Date and time of submission	
Patient Cloud Open Date & Time	17 NOV 2022 00:01
Patient Cloud Close Date & Time	21 NOV 2022 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT	DAY 775
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

[Patient Cloud Open Date & Time](#)

24 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2022 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

Date and time of submission	
Patient Cloud Open Date & Time	08 DEC 2022 00:01
Patient Cloud Close Date & Time	12 DEC 2022 23:59

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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

Date and time of submission	
Patient Cloud Open Date & Time	15 DEC 2022 00:01
Patient Cloud Close Date & Time	19 DEC 2022 23:59

US3482286

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:51:52

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		27 FEB 2021 17:00:46

US3482286

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 23:34:51

Generated On: 09 Jun 2021 17:51:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482286

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 23:34:51

Generated On: 09 Jun 2021 17:51:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482286

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 23:34:51

Generated On: 09 Jun 2021 17:51:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482286

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 23:34:51

Generated On: 09 Jun 2021 17:51:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482286

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 23:34:51

Generated On: 09 Jun 2021 17:51:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482286

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 23:34:51

Generated On: 09 Jun 2021 17:51:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482286

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 17 Apr 2021 03:11:40

Generated On: 09 Jun 2021 17:51:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482286

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 16:20:28

Generated On: 09 Jun 2021 17:51:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482286

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:51:52

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3482286

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

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

US3482286

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:51:52

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.

US3482286

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:51:52

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

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

US3482286

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:51:52

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID-19 Contact

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

Date of Contact	08 JAN 2021
Time of Contact	08:10
Date and Time of Contact (derived)	08 JAN 2021 08:10
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input checked="" type="checkbox"/></div> <div>Safety Call<input type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

Symptom Day

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

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" 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 type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

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

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

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

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Form: Symptom Log (2)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

Symptom Day

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

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Form: Symptom Log (2)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" 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 type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (2)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

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

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

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

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

Symptom Day

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

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" 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 type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (3)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

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

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Form: Symptom Log (3)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

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

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Form: Symptom Log (4)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

Symptom Day

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

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Form: Symptom Log (4)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" 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 type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

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

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Form: Symptom Log (4)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

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

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Form: Symptom Log (5)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

Symptom Day

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

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Form: Symptom Log (5)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	93 %	
O2 Saturation Units	%	
Temperature	98.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

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

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

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

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Form: Symptom Log (6)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

Symptom Day

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

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Form: Symptom Log (6)

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	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	09 JAN 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (6)

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

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Form: Symptom Log (6)

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

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Form: Symptom Log (7)

Data signed: (b) (4) 01 Apr 2021 23:34:50

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Symptom Day

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

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Form: Symptom Log (7)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (7)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

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

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Form: Symptom Log (7)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

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

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Form: Symptom Log (8)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

Symptom Day

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

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Form: Symptom Log (8)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	98.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (8)

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

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Form: Symptom Log (8)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Form: Symptom Log (9)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

Symptom Day

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

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Form: Symptom Log (9)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	101.5 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input 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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Form: Symptom Log (9)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

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

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Form: Symptom Log (9)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Form: Symptom Log (10)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

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 08 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

	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 JAN 2021
------	-------------

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

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

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

Temperature	100.1 F
-------------	---------

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

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

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

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

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

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

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

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 ☐

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

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"/>

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (11)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

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

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

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

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

Symptom Day

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

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Form: Symptom Log (12)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (12)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

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

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

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Generated On: 09 Jun 2021 17:51:52

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Form: Symptom Log (13)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

Symptom Day

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

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Form: Symptom Log (13)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Form: Symptom Log (13)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

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

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Form: Symptom Log (13)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

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

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

Symptom Day

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

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Form: Symptom Log (14)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

	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 JAN 2021
------	-------------

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

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

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

Temperature	97.8 F
-------------	--------

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

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

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

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

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Form: Symptom Log (14)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

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

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

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

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

Symptom Day

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

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

	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 JAN 2021
------	-------------

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

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

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

Temperature	97.8 F
-------------	--------

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

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

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

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

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

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

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

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

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

Symptom Day

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

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	19 JAN 2021	
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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

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

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

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

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

Symptom Day

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

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	20 JAN 2021	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

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

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

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

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

Symptom Day

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

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	21 JAN 2021	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

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

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

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

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Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

Date of Visit	08 JAN 2021
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of Test	08 JAN 2021
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	1

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

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

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

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

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

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

If Yes, provide:

Start Date 08 JAN 2021

End Date 08 JAN 2021

Oxygen Saturation 93 %

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

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

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

Start Date _____

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

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

Ventilator Support:

High-Flow Oxygen?

Yes ☐

No ☒

Start Date

End Date

Non-Invasive Ventilation?

Yes ☐

No ☒

Start Date

End Date

Mechanical Ventilation?

Yes ☐

No ☒

Start Date

End Date

ECMO?

Yes ☐

No ☒

Start Date

End Date

Evidence of Shock:

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

Yes ☐

No ☒

Start Date

End Date

Evidence of Shock Requires Vasopressors

Yes ☐

No ☒

Start Date

End Date

Acute Renal Dysfunction?

Yes ☐

No ☒

Start Date

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 01 Apr 2021 23:34:50

Generated On: 09 Jun 2021 17:51:52

Hepatic Dysfunction? Yes ☐
No ☒

Start Date

Neurologic Dysfunction? Yes ☐
No ☒

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☐
No ☒

Date of Assessment

Radiographical Evidence Yes ☐
No ☒

Date of Assessment

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

Start Date

End Date

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Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 01 Apr 2021 23:34:51

Generated On: 09 Jun 2021 17:51:52

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	10 JAN 2021
Day 5	Yes	12 JAN 2021
Day 7	Yes	14 JAN 2021
Day 9	Yes	16 JAN 2021
Day 14	Yes	21 JAN 2021
Day 21	Yes	27 JAN 2021
Day 28	Yes	10 FEB 2021

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 23:34:51

Generated On: 09 Jun 2021 17:51:52

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

Visit date (dd MMM yyyy)	08 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	SICKD1
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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 23:34:51

Generated On: 09 Jun 2021 17:51:52

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	08 JAN 2021
Time of assessment (00:00-23:59)	08:19 (24 HR)
Vital Signs Date and Time (derived)	08 JAN 2021 08:19
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 23:34:51

Generated On: 09 Jun 2021 17:51:52

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 JAN 2021

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

US3482286

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 01 Apr 2021 23:34:51

Generated On: 09 Jun 2021 17:51:52

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

08 JAN 2021

US3482286

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 22:33:35

Generated On: 09 Jun 2021 17:51:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 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	SICKD28

US3482286

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Mar 2021 22:33:35

Generated On: 09 Jun 2021 17:51:52

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 FEB 2021
Time of assessment (00:00-23:59)	09:13 (24 HR)
Vital Signs Date and Time (derived)	10 FEB 2021 09:13
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
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)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3482286

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 22:33:35

Generated On: 09 Jun 2021 17:51:52

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 FEB 2021

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

US3482286

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 26 Mar 2021 22:33:35

Generated On: 09 Jun 2021 17:51:52

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

10 FEB 2021

US3482286

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

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 23:34:51

Generated On: 09 Jun 2021 17:51:52

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

Visit date (dd MMM yyyy)	10 FEB 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3482286

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

Form: Unblinding

Data signed: (b) (4) 01 Apr 2021 23:34:51

Generated On: 09 Jun 2021 17:51:52

Date of updated informed consent (<i>dd MMM yyyy</i>)	10 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>)	10 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

US3482286

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 01 Apr 2021 23:34:51

Generated On: 09 Jun 2021 17:51:52

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

US3482286

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 01 Apr 2021 23:34:51

Generated On: 09 Jun 2021 17:51:52

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)	10 FEB 2021
Time of assessment (00:00-23:59)	09:13 (24 HR)
Vital Signs Date and Time (derived)	10 FEB 2021 09:13
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)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3482286

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 01 Apr 2021 23:34:51

Generated On: 09 Jun 2021 17:51:52

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)	10 FEB 2021
Time of assessment (00:00-23:59)	10:45 (24 HR)
Vital Signs Date and Time (derived)	10 FEB 2021 10:45
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3482286

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

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 23:34:51

Generated On: 09 Jun 2021 17:51:52

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 FEB 2021

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

US3482286

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

Form: Exposure

Data signed: (b) (4) 01 Apr 2021 23:34:51

Generated On: 09 Jun 2021 17:51:52

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) 10 FEB 2021

What was the treatment time? (00:00-23:59) 10:13 (24 HR)

Treatment Date and Time (derived) 10 FEB 2021 10:13

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

US3482286

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Apr 2021 23:34:51

Generated On: 09 Jun 2021 17:51:52

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	10 FEB 2021
Collection time (00:00-23:59)	09:52 (24 HR)
Collection date and time (derived)	10 FEB 2021 09:52

US3482286

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 01 Apr 2021 23:34:51

Generated On: 09 Jun 2021 17:51:52

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	10 FEB 2021
Collection time (00:00 - 23:59)	09:55
Collection Date and Time (derived)	10 FEB 2021 09:55

US3482286

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

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 23:34:51

Generated On: 09 Jun 2021 17:51:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482286

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 23:34:51

Generated On: 09 Jun 2021 17:51:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482286

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 23:34:51

Generated On: 09 Jun 2021 17:51:52

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

US3482286

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 23:34:51

Generated On: 09 Jun 2021 17:51:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 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

US3482286

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 01 Apr 2021 23:34:51

Generated On: 09 Jun 2021 17:51:52

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)	12 MAR 2021
Time of assessment (00:00-23:59)	08:10 (24 HR)
Vital Signs Date and Time (derived)	12 MAR 2021 08:10
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3482286

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 01 Apr 2021 23:34:51

Generated On: 09 Jun 2021 17:51:52

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)	12 MAR 2021
Time of assessment (00:00-23:59)	09:00 (24 HR)
Vital Signs Date and Time (derived)	12 MAR 2021 09:00
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)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3482286

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 23:34:51

Generated On: 09 Jun 2021 17:51:52

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 MAR 2021

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

US3482286

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 01 Apr 2021 23:34:51

Generated On: 09 Jun 2021 17:51:52

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) 12 MAR 2021

What was the treatment time? (00:00-23:59) 08:30 (24 HR)

Treatment Date and Time (derived) 12 MAR 2021 08:30

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

US3482286

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 23:34:51

Generated On: 09 Jun 2021 17:51:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482286

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 23:34:51

Generated On: 09 Jun 2021 17:51:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482286

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 23:34:51

Generated On: 09 Jun 2021 17:51:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482286

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:51:52

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

US3482286

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:51:52

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3482286

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:51:52

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.

US3482286

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:51:52

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

7 APR 2021

Collection time (00:00-23:59)

08:40 (24 HR)

Collection date and time (derived)

7 APR 2021 08:40

US3482286

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 13 Mar 2021 03:25:52

Generated On: 09 Jun 2021 17:51:52

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3482286

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 13 Mar 2021 03:25:52

Generated On: 09 Jun 2021 17:51:52

AEID	USA-US106-2021-MRNA-1273-P30 1000010
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)	04 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)	14 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input 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"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 13 Mar 2021 03:25:52

Generated On: 09 Jun 2021 17:51:52

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	PARTICIPANT WITH COVID SX AS PER SX LOG; HAD 2 INSTANCES WITH PULSE OX MEETING "SEVERE" CRITERIA PER PROTOCOL (SPO2 <= 93%) .
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
PRODUCTION RELEASE (v12.003 EAB) (1725)	

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 13 Mar 2021 03:25:52

Generated On: 09 Jun 2021 17:51:52

Admitted to ICU Derived (CSA Programming Field Only)

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 26 Mar 2021 22:33:34

Generated On: 09 Jun 2021 17:51:52

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

Yes ☒

No ☐

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

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Mar 2021 22:33:34

Generated On: 09 Jun 2021 17:51:52

Name of Medication MOTRIN

Prophylaxis Yes ☐
No ☒

Indication BODY ACHES RELATED TO
COVID-19

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Mar 2021 22:33:34

Generated On: 09 Jun 2021 17:51:52

	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 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		06 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Mar 2021 22:33:34

Generated On: 09 Jun 2021 17:51:52

Name of Medication VITAMIN D

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENTATION

Dose per administration UNK

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

If dose unit is Other, specify UNK

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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US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Mar 2021 22:33:34

Generated On: 09 Jun 2021 17:51:52

	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 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	28 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Mar 2021 22:33:34

Generated On: 09 Jun 2021 17:51:52

Name of Medication VITAMIN C

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENTATION

Dose per administration UNK

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

If dose unit is Other, specify UNK

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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US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Mar 2021 22:33:34

Generated On: 09 Jun 2021 17:51:52

	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 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	28 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Mar 2021 22:33:34

Generated On: 09 Jun 2021 17:51:52

Name of Medication ZINC

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENTATION

Dose per administration UNK

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

If dose unit is Other, specify UNK

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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US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Mar 2021 22:33:34

Generated On: 09 Jun 2021 17:51:52

	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 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	28 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Mar 2021 22:33:34

Generated On: 09 Jun 2021 17:51:52

Name of Medication MOTRIN

Prophylaxis Yes ☐
No ☒

Indication BODY ACHES RELATED TO
COVID-19

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 ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Mar 2021 22:33:34

Generated On: 09 Jun 2021 17:51:52

	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)		10 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		15 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3482286

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 26 Mar 2021 22:33:34

Generated On: 09 Jun 2021 17:51:52

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3482286

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:51:52

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3482286

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:51:52

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 ☐

US3482286

Folder: SAE USA-US106-2021-MRNA-1273-P301000010

Form: Safety Report Form

Data signed: (b) (4) 26 Mar 2021 22:33:35

Generated On: 09 Jun 2021 17:51:52

SAEID	USA-US106-2021-MRNA-1273-P301000010
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	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3482286

Folder: SAE USA-US106-2021-MRNA-1273-P301000010

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Mar 2021 22:33:35

Generated On: 09 Jun 2021 17:51:52

SAEID	USA-US106-2021-MRNA-1273-P301000010
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	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	03/FEB/2021 16:45
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

US3482286

Folder: SAE USA-US106-2021-MRNA-1273-P301000010

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Mar 2021 22:33:35

Generated On: 09 Jun 2021 17:51:52

SAEID	USA-US106-2021-MRNA-1273-P301000010
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	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	04/MAR/2021 16:12
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

US3482286 (Prod: Hope Clinic of The Emory Vaccine Center)

US3482286

Form: Participant Creation

Generated On: 09 Jun 2021 17:51:52

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:40
User entered 'US3482286'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Oct 2020 13:38:38

US3482286

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:51:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered 'Yes (Y)'	Amy Anderson (b) (4)	13 Oct 2020 14:56:55

US3482286

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered '13 OCT 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Oct 2020 13:38:40

US3482286

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:51:52

[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 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered 'Clinic (Clinic)'	Amy Anderson (b) (4)	13 Oct 2020 14:56:55

US3482286

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:51:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User entered 'SCRN'	System	13 Oct 2020 14:56:55

US3482286

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:00:50
User entered (b) (6) 1968'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Oct 2020 13:38:41

US3482286

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:51:52

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:00:50
User entered '52'	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 14:57:24

US3482286

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:51:52

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User entered 'YEARS'	System	13 Oct 2020 14:57:24

US3482286

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:51:52

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User entered '52'	System	13 Oct 2020 15:09:46

US3482286

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:51:52

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:00:50
User entered 'Male (M)'	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 14:57:24

US3482286

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:51:52

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:00:50
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 14:57:24

US3482286

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:51:52

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:00:50
User entered '0'	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 14:57:24

US3482286

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:51:52

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:00:50
User entered 'l'	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 14:57:24

US3482286

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:51:52

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:00:50
User entered 'l'	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 14:57:24

US3482286

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:51:52

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:00:50
User entered '0'	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 14:57:24

US3482286

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:51:52

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:00:50
User entered '0'	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 14:57:24

US3482286

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:51:52

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:00:50
User entered '0'	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 14:57:24

US3482286

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:51:52

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:00:50
User entered empty.	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 14:57:24

US3482286

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:51:52

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:00:50
User entered '0'	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 14:57:24

US3482286

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:51:52

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:00:50
User entered '0'	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 14:57:24

US3482286

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:51:52

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:07:09
User entered '13 Oct 2020'	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 15:09:46

US3482286

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User entered 'Oct 2020'	System	13 Oct 2020 15:09:46

US3482286

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User entered '2020'	System	13 Oct 2020 15:09:46

US3482286

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:51:52

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:07:09
User entered 'Amendment 4 (4)'	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 15:09:46

US3482286

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:07:09
User entered 'Yes (Y)'	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 15:09:46

US3482286

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:51:52

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:07:09
User entered empty.	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 15:09:46

US3482286

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:51:52

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:07:09
User entered empty.	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 15:09:46

US3482286

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:51:52

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:07:09
User entered 'No (N)'	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 15:09:46

US3482286

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:51:52

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:07:09
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	13 Oct 2020 13:38:40

US3482286

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:51:52

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User entered 'I'	System	13 Oct 2020 15:09:46

US3482286

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:07:39
User entered 'Yes (Y)'	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 14:59:36

US3482286

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:51:52

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered 'Yes (Y)'	(b) (4) Amy Anderson (b) (4)	13 Oct 2020 16:06:54

US3482286

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:51:52

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 12:53:52
' (Site from DM).		
Query 'Per DM CLR: Please note that there is no Con Amy Anderson Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.	(b) (4) (b) (4)	26 Oct 2020 12:12:32
' answered with 'correct. there is no con med. patient not taking any meds for it.' (Site from DM).		
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.	(b) (4), (b) (6)	26 Oct 2020 09:39:25
' (Site from DM).		
User coded data point as SOC: Investigations, HLGT: Cardiac and vascular investigations (excl enzyme tests), HLT: Vascular tests NEC (incl blood pressure), PT: Blood pressure increased, LLT: Increased blood pressure - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 16:08:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 16:08:13
Data point term sent to Coder	System	13 Oct 2020 16:07:49
User entered 'elevated blood pressure'	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 16:07:39

US3482286

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered empty.	(b) (4) Amy Anderson (b) (4)	13 Oct 2020 16:07:39

US3482286

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:51:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered 'I'	Amy Anderson (b) (4)	13 Oct 2020 16:07:39

US3482286

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:51:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered 'Yes (Y)'	(b) (4) Amy Anderson (b) (4)	13 Oct 2020 16:07:39

US3482286

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered empty.	(b) (4) Amy Anderson (b) (4)	13 Oct 2020 16:07:39

US3482286

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:51:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered '0'	Amy Anderson (b) (4)	13 Oct 2020 16:07:39

US3482286

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User entered empty.	System	13 Oct 2020 16:07:39

US3482286

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:51:52

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User entered empty.	System	13 Oct 2020 16:07:39

US3482286

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User entered empty.	System	13 Oct 2020 16:07:39

US3482286

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User entered empty.	System	13 Oct 2020 16:07:39

US3482286

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:13:54
User entered 'Yes (Y)'	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 16:12:52

US3482286

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:13:56
User entered '13 Oct 2020'	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 16:12:52

US3482286

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:13:59
User entered '09:15'	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 16:12:52

US3482286

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User entered '13 Oct 2020 09:15'	System	13 Oct 2020 16:12:52

US3482286

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:14:02
User entered '71' in	Amy Anderson (b) (4)	13 Oct 2020 16:12:52
DataPoint set to visible.	(b) (4) System	13 Oct 2020 15:09:46

US3482286

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:14:04
User entered '186' lb	Amy Anderson (b) (4)	13 Oct 2020 16:12:52
DataPoint set to visible.	(b) (4) System	13 Oct 2020 15:09:46

US3482286

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User entered '25.99598'	System	13 Oct 2020 16:12:52
DataPoint set to visible.	System	13 Oct 2020 15:09:46

US3482286

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User entered 'kg/m2'	System	13 Oct 2020 16:12:52
DataPoint set to visible.	System	13 Oct 2020 15:09:46

US3482286

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:14:07
User entered missing code ND - Not Done.	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 16:12:52

US3482286

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:14:09
User entered empty.	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 16:12:52

US3482286

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:14:12
User entered empty.	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 16:12:52

US3482286

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:14:12
User entered missing code ND - Not Done.	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 16:12:52

US3482286

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User entered 'bpm'	System	13 Oct 2020 16:12:52

US3482286

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:14:12
User entered missing code ND - Not Done.	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 16:12:52

US3482286

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User entered 'breaths/min'	System	13 Oct 2020 16:12:52

US3482286

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:14:12
User entered missing code ND - Not Done.	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 16:12:52

US3482286

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User entered 'mmHg'	System	13 Oct 2020 16:12:52

US3482286

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:14:12
User entered missing code ND - Not Done.	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 16:12:52

US3482286

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User entered 'mmHg'	System	13 Oct 2020 16:12:52

US3482286

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50

US3482286

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50

US3482286

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:51:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered 'Yes (Y)'	Amy Anderson (b) (4)	13 Oct 2020 16:13:19

US3482286

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:51:52

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered '13 Oct 2020'	(b) (4) Amy Anderson (b) (4)	13 Oct 2020 16:13:19

US3482286

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:51:52

[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 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:15:32
User entered 'No (N)'	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 16:14:40

US3482286

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:51:52

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 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:15:34
User entered 'No (N)'	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 16:14:40

US3482286

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:51:52

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 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:15:34
User entered 'No (N)'	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 16:14:40

US3482286

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:51:52

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 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:15:34
User entered 'No (N)'	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 16:14:40

US3482286

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:51:52

[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 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:15:34
User entered 'No (N)'	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 16:14:40

US3482286

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:51:52

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 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:15:34
User entered 'No (N)'	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 16:14:40

US3482286

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:51:52

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 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:15:34
User entered 'No (N)'	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 16:14:40

US3482286

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:51:52

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 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:15:34
User entered 'No (N)'	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 16:14:40

US3482286

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:51:52

[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 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:15:34
User entered 'No (N)'	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 16:14:40

US3482286

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:51:52

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 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:15:34
User entered 'No (N)'	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 16:14:40

US3482286

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:51:52

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 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:15:34
User entered 'No (N)'	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 16:14:40

US3482286

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:51:52

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:15:34
User entered 'No (N)'	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 16:14:40

US3482286

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:51:52

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:15:34
User entered empty.	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 16:14:40

US3482286

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:51:52

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered '0'	(b) (4) Amy Anderson (b) (4)	13 Oct 2020 16:14:40

US3482286

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:51:52

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:15:34
User entered '0'	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 16:14:40

US3482286

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:51:52

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 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:15:34
User entered '0'	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 16:14:40

US3482286

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:51:52

[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 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:15:34
User entered '0'	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 16:14:40

US3482286

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:51:52

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 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:15:34
User entered '0'	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 16:14:40

US3482286

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:51:52

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:15:34
User entered 'l'	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 16:14:40

US3482286

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:51:52

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered 'I'	Amy Anderson (b) (4)	13 Oct 2020 16:14:40

US3482286

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:51:52

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:04:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:15:34
User entered 'Resides in a community with ongoing person to person to transmission'	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 16:14:40

US3482286

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:51:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered 'Yes (Y)'	(b) (4) Amy Anderson (b) (4)	13 Oct 2020 14:59:59

US3482286

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:51:52

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered '13 Oct 2020'	(b) (4) Amy Anderson (b) (4)	13 Oct 2020 14:59:59

US3482286

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:51:52

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered 'Clinic (Clinic)'	(b) (4) Amy Anderson (b) (4)	13 Oct 2020 14:59:59

US3482286

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:51:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User entered 'VISIT1'	System	13 Oct 2020 14:59:59

US3482286

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:19:51
User entered '13 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Oct 2020 14:23:45

US3482286

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:51:52

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:19:51
User entered '113373'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Oct 2020 14:23:45

US3482286

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:51:52

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:19:51
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Oct 2020 14:23:45

US3482286

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:51:52

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)	03 Apr 2021 15:04:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:19:51
User entered 'No (N)'	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 15:07:12

US3482286

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:51:52

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)	03 Apr 2021 15:04:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:19:51
User entered 'No (N)'	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 15:07:12

US3482286

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:51:52

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:19:51
User entered 'No (N)'	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 15:07:12

US3482286

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:51:52

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:19:51
User entered 'No (N)'	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 15:07:12

US3482286

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:51:52

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:19:51
User entered 'No (N)'	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 15:07:12

US3482286

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:51:52

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:19:51
User entered 'No (N)'	Amy Anderson (b) (4)	13 Oct 2020 16:15:02
DataPoint set to visible.	(b) (4) System	13 Oct 2020 15:09:46

US3482286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:51:52

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered missing code ND - Not Done.	(b) (4) Amy Anderson (b) (4)	13 Oct 2020 16:16:54

US3482286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:51:52

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered missing code ND - Not Done.	(b) (4) Amy Anderson (b) (4)	13 Oct 2020 16:16:54

US3482286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:51:52

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered missing code ND - Not Done.	(b) (4) Amy Anderson (b) (4)	13 Oct 2020 16:16:54

US3482286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:51:52

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered missing code ND - Not Done.	(b) (4) Amy Anderson (b) (4)	13 Oct 2020 16:16:54

US3482286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User accepted default value 'Pre-Dose (PREDOSE)'	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 16:16:54

US3482286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered 'Yes (Y)'	(b) (4) Amy Anderson (b) (4)	13 Oct 2020 16:16:54

US3482286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered '13 Oct 2020'	(b) (4) Amy Anderson (b) (4)	13 Oct 2020 16:16:54

US3482286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered '09:15'	(b) (4) Amy Anderson (b) (4)	13 Oct 2020 16:16:54

US3482286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User entered '13 Oct 2020 09:15'	System	13 Oct 2020 16:16:54

US3482286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered '98.9' F	(b) (4) Amy Anderson (b) (4)	13 Oct 2020 16:16:54

US3482286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered 'Oral (Oral)'	(b) (4) Amy Anderson (b) (4) (b) (4)	13 Oct 2020 16:16:54

US3482286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered empty.	(b) (4) Amy Anderson (b) (4)	13 Oct 2020 16:16:54

US3482286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered '77'	(b) (4) Amy Anderson (b) (4)	13 Oct 2020 16:16:54

US3482286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User entered 'bpm'	System	13 Oct 2020 16:16:54

US3482286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered '14'	(b) (4) Amy Anderson (b) (4)	13 Oct 2020 16:16:54

US3482286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User entered 'breaths/min'	System	13 Oct 2020 16:16:54

US3482286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered '142' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	14 Oct 2020 15:10:53
User entered '150'	(b) (4)	
	Amy Anderson (b) (4)	13 Oct 2020 16:16:54
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User entered 'mmHg'	System	13 Oct 2020 16:16:54

US3482286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	(b) (4)	
	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
	(b) (4)	
User entered '98' reason for change: Data Entry Error	Amy Anderson (b) (4)	14 Oct 2020 15:10:53
	(b) (4)	
User entered '97'	Amy Anderson (b) (4)	13 Oct 2020 16:16:54
	(b) (4)	

US3482286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User entered 'mmHg'	System	13 Oct 2020 16:16:54

US3482286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:51:52

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered missing code ND - Not Done.	(b) (4) Amy Anderson (b) (4)	13 Oct 2020 16:16:54

US3482286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:51:52

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered missing code ND - Not Done.	(b) (4) Amy Anderson (b) (4)	13 Oct 2020 16:16:54

US3482286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User accepted default value 'Post-Dose (POSTDOSE)'	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 16:16:54

US3482286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered 'Yes (Y)'	(b) (4) Amy Anderson (b) (4)	13 Oct 2020 16:16:54

US3482286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered '13 Oct 2020'	(b) (4) Amy Anderson (b) (4)	13 Oct 2020 16:16:54

US3482286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered '11:15'	(b) (4) Amy Anderson (b) (4)	13 Oct 2020 16:16:54

US3482286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User entered '13 Oct 2020 11:15'	System	13 Oct 2020 16:16:54

US3482286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered '98.8' F	(b) (4) Amy Anderson (b) (4)	13 Oct 2020 16:16:54

US3482286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered 'Oral (Oral)'	(b) (4) Amy Anderson (b) (4) (b) (4)	13 Oct 2020 16:16:54

US3482286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered empty.	(b) (4) Amy Anderson (b) (4)	13 Oct 2020 16:16:54

US3482286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered '75'	(b) (4) Amy Anderson (b) (4)	13 Oct 2020 16:16:54

US3482286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User entered 'bpm'	System	13 Oct 2020 16:16:54

US3482286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered '16'	(b) (4) Amy Anderson (b) (4)	13 Oct 2020 16:16:54

US3482286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User entered 'breaths/min'	System	13 Oct 2020 16:16:54

US3482286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered '151'	(b) (4) Amy Anderson (b) (4)	13 Oct 2020 16:16:54

US3482286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User entered 'mmHg'	System	13 Oct 2020 16:16:54

US3482286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered '98'	(b) (4) Amy Anderson (b) (4)	13 Oct 2020 16:16:54

US3482286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User entered 'mmHg'	System	13 Oct 2020 16:16:54

US3482286

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:51:52

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 16:25:40
User entered 'Yes (Y)' reason for change: Data Entry Error	Amy Anderson (b) (4)	13 Oct 2020 16:25:40
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	13 Oct 2020 16:17:07
	Amy Anderson (b) (4)	13 Oct 2020 16:17:07
	(b) (4)	

US3482286

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:51:52

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered '13 Oct 2020'	(b) (4) Amy Anderson (b) (4)	13 Oct 2020 16:17:07

US3482286

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:51:52

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:21:55
User entered 'Yes (Y)'	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 15:10:50

US3482286

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:51:52

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:21:55
User entered empty.	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 15:10:50

US3482286

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:21:55
User entered empty.	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 15:10:50

US3482286

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:51:52

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User entered 'MRNA-1273 OR PLACEBO'	System	13 Oct 2020 15:10:50

US3482286

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:51:52

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:21:55
User entered '13 Oct 2020'	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 15:10:50

US3482286

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:51:52

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:21:55
User entered '10:40'	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 15:10:50

US3482286

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:51:52

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User entered '13 Oct 2020 10:40'	System	13 Oct 2020 15:10:50

US3482286

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:51:52

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:21:55
User entered 'Left Arm (LEFT ARM)'	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 15:10:50

US3482286

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:51:52

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:21:55
User entered 'ONCE'	System	13 Oct 2020 15:10:50

US3482286

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:51:52

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User entered 'INTRAMUSCULAR'	System	13 Oct 2020 15:10:50

US3482286

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:51:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered 'Yes (Y)'	(b) (4) Amy Anderson (b) (4)	13 Oct 2020 16:17:40

US3482286

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:51:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered '13 Oct 2020'	(b) (4) Amy Anderson (b) (4)	13 Oct 2020 16:17:40

US3482286

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:51:52

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered '10:10'	(b) (4) Amy Anderson (b) (4)	13 Oct 2020 16:17:40

US3482286

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:51:52

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User entered '13 Oct 2020 10:10'	System	13 Oct 2020 16:17:40

US3482286

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:51:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered '13 Oct 2020'	(b) (4) Amy Anderson (b) (4)	13 Oct 2020 16:18:06

US3482286

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:51:52

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 16:18:06

US3482286

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:51:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered 'Yes (Y)'	(b) (4) Amy Anderson (b) (4)	13 Oct 2020 16:18:06

US3482286

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:51:52

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered '10:15'	(b) (4) Amy Anderson (b) (4)	13 Oct 2020 16:18:06

US3482286

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:51:52

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User entered '13 Oct 2020 10:15'	System	13 Oct 2020 16:18:06

US3482286

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:51:52

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Amy Anderson (b) (4) (b) (4)	13 Oct 2020 16:18:06

US3482286

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:51:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered 'No (N)'	(b) (4) Amy Anderson (b) (4)	13 Oct 2020 16:18:06

US3482286

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:51:52

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered empty.	(b) (4) Amy Anderson (b) (4)	13 Oct 2020 16:18:06

US3482286

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:51:52

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User entered empty.	System	13 Oct 2020 16:18:06

US3482286

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:51:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered 'Yes (Y)'	(b) (4) Amy Anderson (b) (4)	13 Oct 2020 16:18:21

US3482286

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:51:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User entered 'I'	System	13 Oct 2020 16:18:21

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
Data entry locked.	System	13 Oct 2020 15:10:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:51:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-13T11:26:50', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '1693c8bf-34bd-4b38-8587-ec59fcf916ae' User entered 'Yes (Y)'	System	13 Oct 2020 15:27:36
	System	13 Oct 2020 15:27:36

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:51:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-13T11:26:55', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '1693c8bf-34bd-4b38-8587-ec59fcf916ae' User entered '98.8'	System	13 Oct 2020 15:27:36
	System	13 Oct 2020 15:27:36

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-13T11:27:00', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '1693c8bf-34bd-4b38-8587-ec59fcf916ae'	System	13 Oct 2020 15:27:36
User entered 'No (N)'	System	13 Oct 2020 15:27:36

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-13T11:27:26', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '1693c8bf-34bd-4b38-8587-ec59fcf916ae' User entered '13 Oct 2020 11:27'	System	13 Oct 2020 15:27:36
	System	13 Oct 2020 15:27:36

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '13 Oct 2020 11:00'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '13 Oct 2020 13:30'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
Data entry locked.	System	13 Oct 2020 15:10:50
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:51:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-13T16:01:49', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '3a55ec3a-3537-4066-a5f5-e89d4ad13119' User entered 'Yes (Y)'	System	13 Oct 2020 20:02:08
	System	13 Oct 2020 20:02:08

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:51:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-13T16:01:56', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '3a55ec3a-3537-4066-a5f5-e89d4ad13119' User entered '97.2'	System	13 Oct 2020 20:02:08
	System	13 Oct 2020 20:02:08

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-13T16:01:59', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '3a55ec3a-3537-4066-a5f5-e89d4ad13119' User entered 'No (N)'	System	13 Oct 2020 20:02:08
	System	13 Oct 2020 20:02:08

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-13T16:02:02', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '3a55ec3a-3537-4066-a5f5-e89d4ad13119' User entered '13 Oct 2020 16:02'	System	13 Oct 2020 20:02:08
	System	13 Oct 2020 20:02:08

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '13 Oct 2020 14:25'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
Data entry locked.	System	13 Oct 2020 15:10:50
User entered 'Day 2'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:51:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-15T08:01:49', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '3ff5f11e-6a73-4e7a-9b65-162f5f141776' User entered 'Yes (Y)'	System	15 Oct 2020 12:02:08
	System	15 Oct 2020 12:02:08

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:51:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-15T08:01:55', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '3ff5f11e-6a73-4e7a-9b65-162f5f141776' User entered '97.7'	System	15 Oct 2020 12:02:08
	System	15 Oct 2020 12:02:08

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-15T08:01:59', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '3ff5f11e-6a73-4e7a-9b65-162f5f141776'	System	15 Oct 2020 12:02:08
User entered 'No (N)'	System	15 Oct 2020 12:02:08

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-15T08:02:03', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '3ff5f11e-6a73-4e7a-9b65-162f5f141776'	System	15 Oct 2020 12:02:08
User entered '15 Oct 2020 08:02'	System	15 Oct 2020 12:02:08

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
Data entry locked.	System	13 Oct 2020 15:10:50
User entered 'Day 3'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:51:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-15T12:00:17', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '1d41ab36-3fb2-4d63-83ef-aab27f613448' User entered 'Yes (Y)'	System	15 Oct 2020 16:00:42
	System	15 Oct 2020 16:00:42

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:51:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-15T12:00:23', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '1d41ab36-3fb2-4d63-83ef-aab27f613448' User entered '97.7'	System	15 Oct 2020 16:00:42
	System	15 Oct 2020 16:00:42

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-15T12:00:26', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '1d41ab36-3fb2-4d63-83ef-aab27f613448'	System	15 Oct 2020 16:00:42
User entered 'No (N)'	System	15 Oct 2020 16:00:42

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-15T12:00:31', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '1d41ab36-3fb2-4d63-83ef-aab27f613448'	System	15 Oct 2020 16:00:42
User entered '15 Oct 2020 12:00'	System	15 Oct 2020 16:00:42

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
Data entry locked.	System	13 Oct 2020 15:10:50
User entered 'Day 4'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:51:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-16T12:55:07', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '4d27d885-5102-4b85-a7d8-aa7f704191d8' User entered 'Yes (Y)'	System	16 Oct 2020 16:55:40
	System	16 Oct 2020 16:55:40

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:51:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-16T12:55:25', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '4d27d885-5102-4b85-a7d8-aa7f704191d8' User entered '97.3'	System	16 Oct 2020 16:55:40
	System	16 Oct 2020 16:55:40

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-16T12:55:30', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '4d27d885-5102-4b85-a7d8-aa7f704191d8' User entered 'No (N)'	System	16 Oct 2020 16:55:40
	System	16 Oct 2020 16:55:40

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-16T12:55:33', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '4d27d885-5102-4b85-a7d8-aa7f704191d8' User entered '16 Oct 2020 12:55'	System	16 Oct 2020 16:55:40
	System	16 Oct 2020 16:55:40

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
Data entry locked.	System	13 Oct 2020 15:10:50
User entered 'Day 5'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:51:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-18T00:54:41', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '41ebb1bd-c6fe-4f35-a245-51add569fc63' User entered 'Yes (Y)'	System	18 Oct 2020 04:54:58
	System	18 Oct 2020 04:54:58

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:51:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-18T00:54:49', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '41ebb1bd-c6fe-4f35-a245-51add569fc63' User entered '97.2'	System	18 Oct 2020 04:54:58
	System	18 Oct 2020 04:54:58

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-18T00:54:52', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '41ebb1bd-c6fe-4f35-a245-51add569fc63'	System	18 Oct 2020 04:54:58
User entered 'No (N)'	System	18 Oct 2020 04:54:58

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-18T00:54:55', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '41ebb1bd-c6fe-4f35-a245-51add569fc63' User entered '18 Oct 2020 00:54'	System	18 Oct 2020 04:54:58
	System	18 Oct 2020 04:54:58

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
Data entry locked.	System	13 Oct 2020 15:10:50
User entered 'Day 6'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:51:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-18T12:19:43', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'a3b22430-845d-432f-be29-af4ff6083328' User entered 'Yes (Y)'	System	20 Oct 2020 12:49:54
	System	20 Oct 2020 12:49:54

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:51:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-18T12:19:54', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'a3b22430-845d-432f-be29-af4ff6083328'	System	20 Oct 2020 12:49:54
User entered '96.8'	System	20 Oct 2020 12:49:54

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-18T12:19:56', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'a3b22430-845d-432f-be29-af4ff6083328'	System	20 Oct 2020 12:49:54
User entered 'No (N)'	System	20 Oct 2020 12:49:54

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-18T12:19:59', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'a3b22430-845d-432f-be29-af4ff6083328'	System	20 Oct 2020 12:49:54
User entered '18 Oct 2020 12:19'	System	20 Oct 2020 12:49:54

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
Data entry locked.	System	13 Oct 2020 15:10:50
User entered 'Day 7'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:51:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-20T08:50:08', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '5b2f0fad-ef93-46fe-b647-f2e441f49332' User entered 'Yes (Y)'	System	20 Oct 2020 12:54:07
	System	20 Oct 2020 12:54:07

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:51:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-20T08:53:59', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '5b2f0fad-ef93-46fe-b647-f2e441f49332' User entered '97.3'	System	20 Oct 2020 12:54:07
	System	20 Oct 2020 12:54:07

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-20T08:54:01', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '5b2f0fad-ef93-46fe-b647-f2e441f49332'	System	20 Oct 2020 12:54:07
User entered 'No (N)'	System	20 Oct 2020 12:54:07

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-20T08:54:04', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '5b2f0fad-ef93-46fe-b647-f2e441f49332' User entered '20 Oct 2020 08:54'	System	20 Oct 2020 12:54:07
	System	20 Oct 2020 12:54:07

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
Data entry locked.	System	13 Oct 2020 15:10:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:51:52

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 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-13T11:27:31', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '755bc89d-2a1c-4d00-864e-d0f439be5e60' User entered 'None (1)'	System	13 Oct 2020 15:27:57
	System	13 Oct 2020 15:27:57

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-13T11:27:34', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '755bc89d-2a1c-4d00-864e-d0f439be5e60'	System	13 Oct 2020 15:27:57
User entered 'No (N)'	System	13 Oct 2020 15:27:57

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-13T11:27:37', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '755bc89d-2a1c-4d00-864e-d0f439be5e60' User entered 'No (N)'	System	13 Oct 2020 15:27:57
	System	13 Oct 2020 15:27:57

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:51:52

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 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-13T11:27:48', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '755bc89d-2a1c-4d00-864e-d0f439be5e60' User entered 'None (1)'	System	13 Oct 2020 15:27:57
	System	13 Oct 2020 15:27:57

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-13T11:27:51', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '755bc89d-2a1c-4d00-864e-d0f439be5e60' User entered '13 Oct 2020 11:27'	System	13 Oct 2020 15:27:57
	System	13 Oct 2020 15:27:57

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '13 Oct 2020 11:00'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '13 Oct 2020 13:30'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
Data entry locked.	System	13 Oct 2020 15:10:50
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:51:52

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 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-13T16:02:09', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'da2e3015-74a5-479e-8cc7-bb351d299671' User entered 'None (1)'	System	13 Oct 2020 20:02:25
	System	13 Oct 2020 20:02:25

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:51:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-13T16:02:13', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'da2e3015-74a5-479e-8cc7-bb351d299671' User entered 'No (N)'	System	13 Oct 2020 20:02:25
	System	13 Oct 2020 20:02:25

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-13T16:02:16', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'da2e3015-74a5-479e-8cc7-bb351d299671' User entered 'No (N)'	System	13 Oct 2020 20:02:25
	System	13 Oct 2020 20:02:25

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:51:52

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 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-13T16:02:20', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'da2e3015-74a5-479e-8cc7-bb351d299671'	System	13 Oct 2020 20:02:25
User entered 'None (1)'	System	13 Oct 2020 20:02:25

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-13T16:02:24', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'da2e3015-74a5-479e-8cc7-bb351d299671' User entered '13 Oct 2020 16:02'	System	13 Oct 2020 20:02:25
	System	13 Oct 2020 20:02:25

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '13 Oct 2020 14:25'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
Data entry locked.	System	13 Oct 2020 15:10:50
User entered 'Day 2'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:51:52

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 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-15T08:02:09', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'c075ffbe-f0fc-41e4-b0f4-e75b4e01dc3a' User entered 'None (1)'	System	15 Oct 2020 12:02:19
	System	15 Oct 2020 12:02:19

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:51:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-15T08:02:11', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'c075ffbe-f0fc-41e4-b0f4-e75b4e01dc3a'	System	15 Oct 2020 12:02:19
User entered 'No (N)'	System	15 Oct 2020 12:02:19

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-15T08:02:13', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'c075ffbe-f0fc-41e4-b0f4-e75b4e01dc3a'	System	15 Oct 2020 12:02:19
User entered 'No (N)'	System	15 Oct 2020 12:02:19

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:51:52

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 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-15T08:02:15', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'c075ffbe-f0fc-41e4-b0f4-e75b4e01dc3a' User entered 'None (1)'	System	15 Oct 2020 12:02:19
	System	15 Oct 2020 12:02:19

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-15T08:02:18', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'c075ffbe-f0fc-41e4-b0f4-e75b4e01dc3a' User entered '15 Oct 2020 08:02'	System	15 Oct 2020 12:02:19
	System	15 Oct 2020 12:02:19

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
Data entry locked.	System	13 Oct 2020 15:10:50
User entered 'Day 3'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:51:52

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 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-15T12:00:36', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'ef4ba990-aaf8-4d9e-9bfc-98d010ab45da'	System	15 Oct 2020 16:01:01
User entered 'None (1)'	System	15 Oct 2020 16:01:01

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:51:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-15T12:00:38', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'ef4ba990-aaf8-4d9e-9bfc-98d010ab45da' User entered 'No (N)'	System	15 Oct 2020 16:01:01
	System	15 Oct 2020 16:01:01

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-15T12:00:40', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'ef4ba990-aaf8-4d9e-9bfc-98d010ab45da' User entered 'No (N)'	System	15 Oct 2020 16:01:01
	System	15 Oct 2020 16:01:01

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:51:52

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 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-15T12:00:43', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'ef4ba990-aaf8-4d9e-9bfc-98d010ab45da' User entered 'None (1)'	System	15 Oct 2020 16:01:01
	System	15 Oct 2020 16:01:01

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-15T12:00:45', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'ef4ba990-aaf8-4d9e-9bfc-98d010ab45da' User entered '15 Oct 2020 12:00'	System	15 Oct 2020 16:01:01
	System	15 Oct 2020 16:01:01

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
Data entry locked.	System	13 Oct 2020 15:10:50
User entered 'Day 4'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:51:52

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 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-16T12:55:37', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'a4acfb2e-3927-43b4-84ef-d29d2b1db14f' User entered 'None (1)'	System	16 Oct 2020 16:55:48
	System	16 Oct 2020 16:55:48

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:51:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-16T12:55:39', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'a4acfb2e-3927-43b4-84ef-d29d2b1db14f' User entered 'No (N)'	System	16 Oct 2020 16:55:48
	System	16 Oct 2020 16:55:48

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-16T12:55:40', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'a4acfb2e-3927-43b4-84ef-d29d2b1db14f' User entered 'No (N)'	System	16 Oct 2020 16:55:48
	System	16 Oct 2020 16:55:48

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:51:52

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 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-16T12:55:42', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'a4acfb2e-3927-43b4-84ef-d29d2b1db14f' User entered 'None (1)'	System	16 Oct 2020 16:55:48
	System	16 Oct 2020 16:55:48

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-16T12:55:45', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'a4acfb2e-3927-43b4-84ef-d29d2b1db14f' User entered '16 Oct 2020 12:55'	System	16 Oct 2020 16:55:48
	System	16 Oct 2020 16:55:48

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
Data entry locked.	System	13 Oct 2020 15:10:50
User entered 'Day 5'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:51:52

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 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-18T00:54:58', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'aabebac2-ef4e-415f-b34c-1ba3cf2698f2'	System	18 Oct 2020 04:55:24
User entered 'None (1)'	System	18 Oct 2020 04:55:24

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:51:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-18T00:55:01', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'aabebac2-ef4e-415f-b34c-1ba3cf2698f2'	System	18 Oct 2020 04:55:24
User entered 'No (N)'	System	18 Oct 2020 04:55:24

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-18T00:55:04', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'aabebac2-ef4e-415f-b34c-1ba3cf2698f2'	System	18 Oct 2020 04:55:24
User entered 'No (N)'	System	18 Oct 2020 04:55:24

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:51:52

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 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-18T00:55:05', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'aabebac2-ef4e-415f-b34c-1ba3cf2698f2'	System	18 Oct 2020 04:55:24
User entered 'None (1)'	System	18 Oct 2020 04:55:24

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-18T00:55:07', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'aabebac2-ef4e-415f-b34c-1ba3cf2698f2' User entered '18 Oct 2020 00:55'	System	18 Oct 2020 04:55:24
	System	18 Oct 2020 04:55:24

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
Data entry locked.	System	13 Oct 2020 15:10:50
User entered 'Day 6'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:51:52

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 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-18T12:20:03', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '1ebece89-81e2-4c47-9383-9acbb3e173f0' User entered 'None (1)'	System	20 Oct 2020 12:49:54
	System	20 Oct 2020 12:49:54

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:51:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-18T12:20:06', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '1ebece89-81e2-4c47-9383-9acbb3e173f0' User entered 'No (N)'	System	20 Oct 2020 12:49:54
	System	20 Oct 2020 12:49:54

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-18T12:20:08', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '1ebece89-81e2-4c47-9383-9acbb3e173f0' User entered 'No (N)'	System	20 Oct 2020 12:49:54
	System	20 Oct 2020 12:49:54

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:51:52

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 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-18T12:20:10', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '1ebece89-81e2-4c47-9383-9acbb3e173f0' User entered 'None (1)'	System	20 Oct 2020 12:49:54
	System	20 Oct 2020 12:49:54

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-18T12:20:12', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '1ebece89-81e2-4c47-9383-9acbb3e173f0' User entered '18 Oct 2020 12:20'	System	20 Oct 2020 12:49:54
	System	20 Oct 2020 12:49:54

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
Data entry locked.	System	13 Oct 2020 15:10:50
User entered 'Day 7'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:51:52

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 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-20T08:54:08', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '0e5f8fdf-a7f8-48a5-99dd-293c6a378e7d' User entered 'None (1)'	System	20 Oct 2020 12:54:18
	System	20 Oct 2020 12:54:18

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:51:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-20T08:54:10', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '0e5f8fdf-a7f8-48a5-99dd-293c6a378e7d' User entered 'No (N)'	System	20 Oct 2020 12:54:18
	System	20 Oct 2020 12:54:18

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-20T08:54:12', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '0e5f8fdf-a7f8-48a5-99dd-293c6a378e7d' User entered 'No (N)'	System	20 Oct 2020 12:54:18
	System	20 Oct 2020 12:54:18

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:51:52

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 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-20T08:54:13', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '0e5f8fdf-a7f8-48a5-99dd-293c6a378e7d' User entered 'None (1)'	System	20 Oct 2020 12:54:18
	System	20 Oct 2020 12:54:18

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-20T08:54:16', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '0e5f8fdf-a7f8-48a5-99dd-293c6a378e7d' User entered '20 Oct 2020 08:54'	System	20 Oct 2020 12:54:18
	System	20 Oct 2020 12:54:18

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
Data entry locked.	System	13 Oct 2020 15:10:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:51:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-13T11:28:04', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '7a978f45-7e96-4b48-a7c5-d29b8ad9f4c8' User entered 'None (0)'	System	13 Oct 2020 15:28:39
	System	13 Oct 2020 15:28:39

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:51:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-13T11:28:15', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '7a978f45-7e96-4b48-a7c5-d29b8ad9f4c8' User entered 'None (0)'	System	13 Oct 2020 15:28:39
	System	13 Oct 2020 15:28:39

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:51:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-13T11:28:19', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '7a978f45-7e96-4b48-a7c5-d29b8ad9f4c8' User entered 'None (0)'	System	13 Oct 2020 15:28:39
	System	13 Oct 2020 15:28:39

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:51:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-13T11:28:21', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '7a978f45-7e96-4b48-a7c5-d29b8ad9f4c8' User entered 'None (0)'	System	13 Oct 2020 15:28:39
	System	13 Oct 2020 15:28:39

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:51:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-13T11:28:25', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '7a978f45-7e96-4b48-a7c5-d29b8ad9f4c8' User entered 'None (0)'	System	13 Oct 2020 15:28:39
	System	13 Oct 2020 15:28:39

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:51:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-13T11:28:27', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '7a978f45-7e96-4b48-a7c5-d29b8ad9f4c8' User entered 'None (0)'	System	13 Oct 2020 15:28:39
	System	13 Oct 2020 15:28:39

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:51:52

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 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-13T11:28:33', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '7a978f45-7e96-4b48-a7c5-d29b8ad9f4c8' User entered 'No (N)'	System	13 Oct 2020 15:28:39
	System	13 Oct 2020 15:28:39

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:51:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-13T11:28:35', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '7a978f45-7e96-4b48-a7c5-d29b8ad9f4c8' User entered '13 Oct 2020 11:28'	System	13 Oct 2020 15:28:39
	System	13 Oct 2020 15:28:39

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '13 Oct 2020 11:00'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '13 Oct 2020 13:30'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
Data entry locked.	System	13 Oct 2020 15:10:50
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:51:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-13T16:02:30', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'bb29520b-cae5-4284-9361-999fedd6972a' User entered 'None (0)'	System	13 Oct 2020 20:03:01
	System	13 Oct 2020 20:03:01

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:51:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-13T16:02:33', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'bb29520b-cae5-4284-9361-999fedd6972a' User entered 'None (0)'	System	13 Oct 2020 20:03:01
	System	13 Oct 2020 20:03:01

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:51:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-13T16:02:36', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'bb29520b-cae5-4284-9361-999fedd6972a' User entered 'None (0)'	System	13 Oct 2020 20:03:01
	System	13 Oct 2020 20:03:01

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:51:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-13T16:02:41', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'bb29520b-cae5-4284-9361-999fedd6972a' User entered 'None (0)'	System	13 Oct 2020 20:03:01
	System	13 Oct 2020 20:03:01

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:51:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-13T16:02:44', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'bb29520b-cae5-4284-9361-999fedd6972a' User entered 'None (0)'	System	13 Oct 2020 20:03:01
	System	13 Oct 2020 20:03:01

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:51:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-13T16:02:46', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'bb29520b-cae5-4284-9361-999fedd6972a' User entered 'None (0)'	System	13 Oct 2020 20:03:01
	System	13 Oct 2020 20:03:01

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:51:52

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 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-13T16:02:56', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'bb29520b-cae5-4284-9361-999fedd6972a' User entered 'No (N)'	System	13 Oct 2020 20:03:01
	System	13 Oct 2020 20:03:01

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:51:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-13T16:02:59', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'bb29520b-cae5-4284-9361-999fedd6972a' User entered '13 Oct 2020 16:02'	System	13 Oct 2020 20:03:01
	System	13 Oct 2020 20:03:01

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '13 Oct 2020 14:25'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
Data entry locked.	System	13 Oct 2020 15:10:50
User entered 'Day 2'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:51:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-15T08:02:21', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'b7a9cb0d-d56d-48f7-b0d9-72be1f54a779' User entered 'None (0)'	System	15 Oct 2020 12:02:36
	System	15 Oct 2020 12:02:36

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:51:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-15T08:02:23', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'b7a9cb0d-d56d-48f7-b0d9-72be1f54a779' User entered 'None (0)'	System	15 Oct 2020 12:02:36
	System	15 Oct 2020 12:02:36

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:51:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-15T08:02:24', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'b7a9cb0d-d56d-48f7-b0d9-72be1f54a779' User entered 'None (0)'	System	15 Oct 2020 12:02:36
	System	15 Oct 2020 12:02:36

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:51:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-15T08:02:26', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'b7a9cb0d-d56d-48f7-b0d9-72be1f54a779' User entered 'None (0)'	System	15 Oct 2020 12:02:36
	System	15 Oct 2020 12:02:36

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:51:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-15T08:02:27', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'b7a9cb0d-d56d-48f7-b0d9-72be1f54a779' User entered 'None (0)'	System	15 Oct 2020 12:02:36
	System	15 Oct 2020 12:02:36

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:51:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-15T08:02:29', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'b7a9cb0d-d56d-48f7-b0d9-72be1f54a779' User entered 'None (0)'	System	15 Oct 2020 12:02:36
	System	15 Oct 2020 12:02:36

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:51:52

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 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-15T08:02:31', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'b7a9cb0d-d56d-48f7-b0d9-72be1f54a779' User entered 'No (N)'	System	15 Oct 2020 12:02:36
	System	15 Oct 2020 12:02:36

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:51:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-15T08:02:34', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'b7a9cb0d-d56d-48f7-b0d9-72be1f54a779' User entered '15 Oct 2020 08:02'	System	15 Oct 2020 12:02:36
	System	15 Oct 2020 12:02:36

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
Data entry locked.	System	13 Oct 2020 15:10:50
User entered 'Day 3'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:51:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-15T12:00:48', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '243ad05a-3ba2-4041-ad1e-e260055fa864' User entered 'None (0)'	System	15 Oct 2020 16:01:42
	System	15 Oct 2020 16:01:42

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:51:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-15T12:00:50', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '243ad05a-3ba2-4041-ad1e-e260055fa864' User entered 'None (0)'	System	15 Oct 2020 16:01:42
	System	15 Oct 2020 16:01:42

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:51:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-15T12:00:52', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '243ad05a-3ba2-4041-ad1e-e260055fa864' User entered 'None (0)'	System	15 Oct 2020 16:01:42
	System	15 Oct 2020 16:01:42

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:51:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-15T12:00:53', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '243ad05a-3ba2-4041-ad1e-e260055fa864' User entered 'None (0)'	System	15 Oct 2020 16:01:42
	System	15 Oct 2020 16:01:42

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:51:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-15T12:00:55', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '243ad05a-3ba2-4041-ad1e-e260055fa864' User entered 'None (0)'	System	15 Oct 2020 16:01:42
	System	15 Oct 2020 16:01:42

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:51:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-15T12:00:56', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '243ad05a-3ba2-4041-ad1e-e260055fa864' User entered 'None (0)'	System	15 Oct 2020 16:01:42
	System	15 Oct 2020 16:01:42

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:51:52

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 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-15T12:00:59', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '243ad05a-3ba2-4041-ad1e-e260055fa864' User entered 'No (N)'	System	15 Oct 2020 16:01:42
	System	15 Oct 2020 16:01:42

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:51:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-15T12:01:01', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '243ad05a-3ba2-4041-ad1e-e260055fa864' User entered '15 Oct 2020 12:01'	System	15 Oct 2020 16:01:42
	System	15 Oct 2020 16:01:42

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
Data entry locked.	System	13 Oct 2020 15:10:50
User entered 'Day 4'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:51:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-16T12:55:49', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'aa929f31-55ac-44a8-90ac-5369fd3930fe' User entered 'None (0)'	System	16 Oct 2020 16:56:07
	System	16 Oct 2020 16:56:07

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:51:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-16T12:55:51', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'aa929f31-55ac-44a8-90ac-5369fd3930fe' User entered 'None (0)'	System	16 Oct 2020 16:56:07
	System	16 Oct 2020 16:56:07

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:51:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-16T12:55:52', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'aa929f31-55ac-44a8-90ac-5369fd3930fe' User entered 'None (0)'	System	16 Oct 2020 16:56:07
	System	16 Oct 2020 16:56:07

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:51:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-16T12:55:54', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'aa929f31-55ac-44a8-90ac-5369fd3930fe' User entered 'None (0)'	System	16 Oct 2020 16:56:07
	System	16 Oct 2020 16:56:07

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:51:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-16T12:55:56', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'aa929f31-55ac-44a8-90ac-5369fd3930fe' User entered 'None (0)'	System	16 Oct 2020 16:56:07
	System	16 Oct 2020 16:56:07

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:51:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-16T12:55:59', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'aa929f31-55ac-44a8-90ac-5369fd3930fe' User entered 'None (0)'	System	16 Oct 2020 16:56:07
	System	16 Oct 2020 16:56:07

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:51:52

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 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-16T12:56:02', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'aa929f31-55ac-44a8-90ac-5369fd3930fe' User entered 'No (N)'	System	16 Oct 2020 16:56:07
	System	16 Oct 2020 16:56:07

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:51:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-16T12:56:04', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'aa929f31-55ac-44a8-90ac-5369fd3930fe' User entered '16 Oct 2020 12:56'	System	16 Oct 2020 16:56:07
	System	16 Oct 2020 16:56:07

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
Data entry locked.	System	13 Oct 2020 15:10:50
User entered 'Day 5'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:51:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-18T00:55:10', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '37bd0efa-d52e-4309-8943-0c5442516153' User entered 'None (0)'	System	20 Oct 2020 12:49:53
	System	20 Oct 2020 12:49:53

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:51:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-18T00:55:12', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '37bd0efa-d52e-4309-8943-0c5442516153' User entered 'None (0)'	System	20 Oct 2020 12:49:53
	System	20 Oct 2020 12:49:53

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:51:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-18T00:55:14', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '37bd0efa-d52e-4309-8943-0c5442516153' User entered 'None (0)'	System	20 Oct 2020 12:49:53
	System	20 Oct 2020 12:49:53

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:51:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-18T00:55:15', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '37bd0efa-d52e-4309-8943-0c5442516153' User entered 'None (0)'	System	20 Oct 2020 12:49:53
	System	20 Oct 2020 12:49:53

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:51:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-18T00:55:16', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '37bd0efa-d52e-4309-8943-0c5442516153' User entered 'None (0)'	System	20 Oct 2020 12:49:53
	System	20 Oct 2020 12:49:53

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:51:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-18T00:55:18', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '37bd0efa-d52e-4309-8943-0c5442516153' User entered 'None (0)'	System	20 Oct 2020 12:49:53
	System	20 Oct 2020 12:49:53

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:51:52

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 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-18T00:55:20', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '37bd0efa-d52e-4309-8943-0c5442516153' User entered 'No (N)'	System	20 Oct 2020 12:49:53
	System	20 Oct 2020 12:49:53

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:51:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-18T00:55:22', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '37bd0efa-d52e-4309-8943-0c5442516153' User entered '18 Oct 2020 00:55'	System	20 Oct 2020 12:49:53
	System	20 Oct 2020 12:49:53

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
Data entry locked.	System	13 Oct 2020 15:10:50
User entered 'Day 6'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:51:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-18T12:20:15', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '952b3adb-9290-46df-9a3d-21180a3f51bd' User entered 'None (0)'	System	20 Oct 2020 12:49:55
	System	20 Oct 2020 12:49:55

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:51:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-18T12:20:17', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '952b3adb-9290-46df-9a3d-21180a3f51bd' User entered 'None (0)'	System	20 Oct 2020 12:49:55
	System	20 Oct 2020 12:49:55

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:51:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-18T12:20:19', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '952b3adb-9290-46df-9a3d-21180a3f51bd' User entered 'None (0)'	System	20 Oct 2020 12:49:55
	System	20 Oct 2020 12:49:55

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:51:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-18T12:20:25', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '952b3adb-9290-46df-9a3d-21180a3f51bd' User entered 'None (0)'	System	20 Oct 2020 12:49:55
	System	20 Oct 2020 12:49:55

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:51:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-18T12:20:27', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '952b3adb-9290-46df-9a3d-21180a3f51bd' User entered 'None (0)'	System	20 Oct 2020 12:49:55
	System	20 Oct 2020 12:49:55

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:51:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-18T12:20:29', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '952b3adb-9290-46df-9a3d-21180a3f51bd' User entered 'None (0)'	System	20 Oct 2020 12:49:55
	System	20 Oct 2020 12:49:55

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:51:52

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 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-18T12:20:31', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '952b3adb-9290-46df-9a3d-21180a3f51bd' User entered 'No (N)'	System	20 Oct 2020 12:49:55
	System	20 Oct 2020 12:49:55

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:51:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-18T12:20:33', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '952b3adb-9290-46df-9a3d-21180a3f51bd' User entered '18 Oct 2020 12:20'	System	20 Oct 2020 12:49:55
	System	20 Oct 2020 12:49:55

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
Data entry locked.	System	13 Oct 2020 15:10:50
User entered 'Day 7'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:51:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-20T08:54:19', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '80ba8d8d-1d1d-44d3-9e2b-afc3b9908521' User entered 'None (0)'	System	20 Oct 2020 12:54:40
	System	20 Oct 2020 12:54:40

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:51:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-20T08:54:20', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '80ba8d8d-1d1d-44d3-9e2b-afc3b9908521' User entered 'None (0)'	System	20 Oct 2020 12:54:40
	System	20 Oct 2020 12:54:40

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:51:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-20T08:54:22', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '80ba8d8d-1d1d-44d3-9e2b-afc3b9908521' User entered 'None (0)'	System	20 Oct 2020 12:54:40
	System	20 Oct 2020 12:54:40

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:51:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-20T08:54:23', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '80ba8d8d-1d1d-44d3-9e2b-afc3b9908521' User entered 'None (0)'	System	20 Oct 2020 12:54:40
	System	20 Oct 2020 12:54:40

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:51:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-20T08:54:24', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '80ba8d8d-1d1d-44d3-9e2b-afc3b9908521' User entered 'None (0)'	System	20 Oct 2020 12:54:40
	System	20 Oct 2020 12:54:40

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:51:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-20T08:54:26', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '80ba8d8d-1d1d-44d3-9e2b-afc3b9908521' User entered 'None (0)'	System	20 Oct 2020 12:54:40
	System	20 Oct 2020 12:54:40

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:51:52

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 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-20T08:54:28', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '80ba8d8d-1d1d-44d3-9e2b-afc3b9908521' User entered 'No (N)'	System	20 Oct 2020 12:54:40
	System	20 Oct 2020 12:54:40

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:51:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-10-20T08:54:31', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '80ba8d8d-1d1d-44d3-9e2b-afc3b9908521' User entered '20 Oct 2020 08:54'	System	20 Oct 2020 12:54:40
	System	20 Oct 2020 12:54:40

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 15:10:50

US3482286

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 15:10:50

US3482286

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:51:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered 'Yes (Y)'	(b) (4) Amy Anderson (b) (4)	20 Oct 2020 17:04:45

US3482286

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered '20 Oct 2020'	(b) (4) Amy Anderson (b) (4)	20 Oct 2020 17:04:45

US3482286

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:51:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Amy Anderson (b) (4)	20 Oct 2020 17:04:45

US3482286

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:51:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered empty.	(b) (4) Amy Anderson (b) (4)	20 Oct 2020 17:04:45

US3482286

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:51:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered 'Yes (Y)'	(b) (4) Amy Anderson (b) (4)	20 Oct 2020 17:04:50

US3482286

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:51:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User entered 'I'	System	20 Oct 2020 17:04:50

US3482286

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:51:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered 'Yes (Y)'	(b) (4) Amy Anderson (b) (4)	28 Oct 2020 14:14:26

US3482286

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered '28 Oct 2020'	(b) (4) Amy Anderson (b) (4)	28 Oct 2020 14:14:26

US3482286

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:51:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Amy Anderson (b) (4)	28 Oct 2020 14:14:26

US3482286

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:51:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered empty.	(b) (4) Amy Anderson (b) (4)	28 Oct 2020 14:14:26

US3482286

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:51:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered 'Yes (Y)'	(b) (4) Amy Anderson (b) (4)	28 Oct 2020 14:14:30

US3482286

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:51:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:04:20
User entered 'I'	System	28 Oct 2020 14:14:30

US3482286

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:51:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:44:10
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered 'Yes (Y)'	(b) (4) Amy Anderson (b) (4)	04 Nov 2020 16:46:52

US3482286

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:44:10
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered '04 Nov 2020'	(b) (4) Amy Anderson (b) (4)	04 Nov 2020 16:46:52

US3482286

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:51:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:44:10
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Amy Anderson (b) (4)	04 Nov 2020 16:46:52

US3482286

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:51:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:44:10
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered empty.	(b) (4) Amy Anderson (b) (4)	04 Nov 2020 16:46:52

US3482286

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:51:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:44:10
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered 'Yes (Y)'	(b) (4) Amy Anderson (b) (4)	04 Nov 2020 16:46:57

US3482286

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:51:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:44:10
User entered 'I'	System	04 Nov 2020 16:46:57

US3482286

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:51:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered 'Yes (Y)'	(b) (4) Amy Anderson (b) (4)	12 Nov 2020 14:00:47

US3482286

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered '12 Nov 2020'	(b) (4) Amy Anderson (b) (4)	12 Nov 2020 14:00:47

US3482286

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:51:52

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered 'Clinic (Clinic)'	(b) (4) Amy Anderson (b) (4)	12 Nov 2020 14:00:47

US3482286

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:51:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User entered 'VISIT2'	System	12 Nov 2020 14:00:47

US3482286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User accepted default value 'Pre-Dose (PREDOSE)'	Amy Anderson (b) (4) (b) (4)	12 Nov 2020 14:43:18

US3482286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered 'Yes (Y)'	(b) (4) Amy Anderson (b) (4)	12 Nov 2020 14:43:18

US3482286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered '12 Nov 2020'	(b) (4) Amy Anderson (b) (4)	12 Nov 2020 14:43:18

US3482286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered '08:15'	(b) (4) Amy Anderson (b) (4)	12 Nov 2020 14:43:18

US3482286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User entered '12 Nov 2020 08:15'	System	12 Nov 2020 14:43:18

US3482286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered '98.2' F	(b) (4) Amy Anderson (b) (4)	12 Nov 2020 14:43:18

US3482286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered 'Oral (Oral)'	(b) (4) Amy Anderson (b) (4)	12 Nov 2020 14:43:18

US3482286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered empty.	(b) (4) Amy Anderson (b) (4)	12 Nov 2020 14:43:18

US3482286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered '73'	(b) (4) Amy Anderson (b) (4)	12 Nov 2020 14:43:18

US3482286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User entered 'bpm'	System	12 Nov 2020 14:43:18

US3482286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered '16'	(b) (4) Amy Anderson (b) (4)	12 Nov 2020 14:43:18

US3482286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User entered 'breaths/min'	System	12 Nov 2020 14:43:18

US3482286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered '141'	(b) (4) Amy Anderson (b) (4)	12 Nov 2020 14:43:18

US3482286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User entered 'mmHg'	System	12 Nov 2020 14:43:18

US3482286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered '92'	(b) (4) Amy Anderson (b) (4)	12 Nov 2020 14:43:18

US3482286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User entered 'mmHg'	System	12 Nov 2020 14:43:18

US3482286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User accepted default value 'Post-Dose (POSTDOSE)'	Amy Anderson (b) (4) (b) (4)	12 Nov 2020 14:43:18

US3482286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered 'Yes (Y)'	(b) (4) Amy Anderson (b) (4)	12 Nov 2020 14:43:18

US3482286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered '12 Nov 2020'	(b) (4) Amy Anderson (b) (4)	12 Nov 2020 14:43:18

US3482286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered '09:30'	(b) (4) Amy Anderson (b) (4)	12 Nov 2020 14:43:18

US3482286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User entered '12 Nov 2020 09:30'	System	12 Nov 2020 14:43:18

US3482286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered '98.4' F	(b) (4) Amy Anderson (b) (4)	12 Nov 2020 14:43:18

US3482286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered 'Oral (Oral)'	(b) (4) Amy Anderson (b) (4)	12 Nov 2020 14:43:18

US3482286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered empty.	(b) (4) Amy Anderson (b) (4)	12 Nov 2020 14:43:18

US3482286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered '64'	(b) (4) Amy Anderson (b) (4)	12 Nov 2020 14:43:18

US3482286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User entered 'bpm'	System	12 Nov 2020 14:43:18

US3482286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered '14'	(b) (4) Amy Anderson (b) (4)	12 Nov 2020 14:43:18

US3482286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User entered 'breaths/min'	System	12 Nov 2020 14:43:18

US3482286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered '129'	(b) (4) Amy Anderson (b) (4)	12 Nov 2020 14:43:18

US3482286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User entered 'mmHg'	System	12 Nov 2020 14:43:18

US3482286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered '93'	(b) (4) Amy Anderson (b) (4)	12 Nov 2020 14:43:18

US3482286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User entered 'mmHg'	System	12 Nov 2020 14:43:18

US3482286

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:51:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered 'Yes (Y)'	(b) (4) Amy Anderson (b) (4)	12 Nov 2020 14:01:01

US3482286

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:51:52

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered '12 Nov 2020'	(b) (4) Amy Anderson (b) (4)	12 Nov 2020 14:01:01

US3482286

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:51:52

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:30:17
User entered 'Yes (Y)'	Amy Anderson (b) (4) (b) (4)	12 Nov 2020 14:07:00

US3482286

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:51:52

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:30:17
User entered empty.	Amy Anderson (b) (4) (b) (4)	12 Nov 2020 14:07:00

US3482286

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:51:52

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)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:30:17
User entered empty.	Amy Anderson (b) (4) (b) (4)	12 Nov 2020 14:07:00

US3482286

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:51:52

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User entered 'MRNA-1273 OR PLACEBO'	System	12 Nov 2020 14:07:00

US3482286

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:51:52

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:30:17
User entered '12 Nov 2020'	Amy Anderson (b) (4) (b) (4)	12 Nov 2020 14:07:00

US3482286

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:51:52

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:30:17
User entered '08:59'	Amy Anderson (b) (4) (b) (4)	12 Nov 2020 14:07:00

US3482286

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:51:52

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User entered '12 Nov 2020 08:59'	System	12 Nov 2020 14:07:00

US3482286

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:51:52

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:30:17
User entered 'Left Arm (LEFT ARM)'	Amy Anderson (b) (4) (b) (4)	12 Nov 2020 14:07:00

US3482286

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:51:52

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:30:17
User entered 'ONCE'	System	12 Nov 2020 14:07:00

US3482286

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:51:52

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User entered 'INTRAMUSCULAR'	System	12 Nov 2020 14:07:00

US3482286

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:51:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered 'Yes (Y)'	(b) (4) Amy Anderson (b) (4)	12 Nov 2020 14:01:21

US3482286

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:51:52

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered '12 Nov 2020'	(b) (4) Amy Anderson (b) (4)	12 Nov 2020 14:01:21

US3482286

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:51:52

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered '8:20'	(b) (4) Amy Anderson (b) (4)	12 Nov 2020 14:01:21

US3482286

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:51:52

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User entered '12 Nov 2020 8:20'	System	12 Nov 2020 14:01:21

US3482286

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:51:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered '12 Nov 2020'	(b) (4) Amy Anderson (b) (4)	12 Nov 2020 14:01:42

US3482286

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:51:52

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Amy Anderson (b) (4) (b) (4)	12 Nov 2020 14:01:42

US3482286

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:51:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered 'Yes (Y)'	(b) (4) Amy Anderson (b) (4)	12 Nov 2020 14:01:42

US3482286

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:51:52

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered '08:23'	(b) (4) Amy Anderson (b) (4)	12 Nov 2020 14:01:42

US3482286

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:51:52

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User entered '12 Nov 2020 08:23'	System	12 Nov 2020 14:01:42

US3482286

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:51:52

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Amy Anderson (b) (4) (b) (4)	12 Nov 2020 14:01:42

US3482286

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:51:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered 'No (N)'	(b) (4) Amy Anderson (b) (4)	12 Nov 2020 14:01:42

US3482286

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:51:52

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered empty.	(b) (4) Amy Anderson (b) (4)	12 Nov 2020 14:01:42

US3482286

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:51:52

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User entered empty.	System	12 Nov 2020 14:01:42

US3482286

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:51:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered 'Yes (Y)'	(b) (4) Amy Anderson (b) (4)	12 Nov 2020 14:01:46

US3482286

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:51:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User entered 'I'	System	12 Nov 2020 14:01:46

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
Data entry locked.	System	12 Nov 2020 14:07:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:51:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-12T09:25:07', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '67f5b9b6-aada-44f8-b9f1-a368437e0e12'	System	12 Nov 2020 14:25:23
User entered 'Yes (Y)'	System	12 Nov 2020 14:25:23

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:51:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-12T09:25:15', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '67f5b9b6-aada-44f8-b9f1-a368437e0e12' User entered '97.2'	System	12 Nov 2020 14:25:23
	System	12 Nov 2020 14:25:23

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-12T09:25:18', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '67f5b9b6-aada-44f8-b9f1-a368437e0e12'	System	12 Nov 2020 14:25:23
User entered 'No (N)'	System	12 Nov 2020 14:25:23

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-12T09:25:21', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '67f5b9b6-aada-44f8-b9f1-a368437e0e12'	System	12 Nov 2020 14:25:23
User entered '12 Nov 2020 09:25'	System	12 Nov 2020 14:25:23

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '12 Nov 2020 09:19'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '12 Nov 2020 11:49'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
Data entry locked.	System	12 Nov 2020 14:07:00
User entered 'Day 1, after vaccination (at home)'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:51:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-12T13:08:54', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '5cc78fb6-b9a8-423e-a601-ae8ececfc8918' User entered 'Yes (Y)'	System	12 Nov 2020 18:09:10
	System	12 Nov 2020 18:09:10

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:51:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-12T13:09:02', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '5cc78fb6-b9a8-423e-a601-ae8ececfc8918' User entered '97.6'	System	12 Nov 2020 18:09:10
	System	12 Nov 2020 18:09:10

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-12T13:09:05', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '5cc78fb6-b9a8-423e-a601-ae8ecec8918'	System	12 Nov 2020 18:09:10
User entered 'No (N)'	System	12 Nov 2020 18:09:10

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-12T13:09:08', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '5cc78fb6-b9a8-423e-a601-ae8ececfc8918'	System	12 Nov 2020 18:09:10
User entered '12 Nov 2020 13:09'	System	12 Nov 2020 18:09:10

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '12 Nov 2020 12:44'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '13 Nov 2020 11:59'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
Data entry locked.	System	12 Nov 2020 14:07:00
User entered 'Day 2'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:51:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-14T07:21:19', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '4be01904-03cf-472b-9e32-f3938a37903f' User entered 'Yes (Y)'	System	14 Nov 2020 12:26:59
	System	14 Nov 2020 12:26:59

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:51:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-14T07:26:50', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '4be01904-03cf-472b-9e32-f3938a37903f' User entered '98.2'	System	14 Nov 2020 12:26:59
	System	14 Nov 2020 12:26:59

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-14T07:26:53', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '4be01904-03cf-472b-9e32-f3938a37903f' User entered 'No (N)'	System	14 Nov 2020 12:26:59
	System	14 Nov 2020 12:26:59

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-14T07:26:57', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '4be01904-03cf-472b-9e32-f3938a37903f' User entered '14 Nov 2020 07:26'	System	14 Nov 2020 12:26:59
	System	14 Nov 2020 12:26:59

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '13 Nov 2020 12:00'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '14 Nov 2020 11:59'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
Data entry locked.	System	12 Nov 2020 14:07:00
User entered 'Day 3'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:51:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-15T09:08:02', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'c82bde86-716e-42ba-aa25-25d606165424' User entered 'Yes (Y)'	System	15 Nov 2020 14:09:56
	System	15 Nov 2020 14:09:56

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:51:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-15T09:09:44', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'c82bde86-716e-42ba-aa25-25d606165424' User entered '97.6'	System	15 Nov 2020 14:09:56
	System	15 Nov 2020 14:09:56

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-15T09:09:48', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'c82bde86-716e-42ba-aa25-25d606165424'	System	15 Nov 2020 14:09:56
User entered 'No (N)'	System	15 Nov 2020 14:09:56

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-15T09:09:53', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'c82bde86-716e-42ba-aa25-25d606165424' User entered '15 Nov 2020 09:09'	System	15 Nov 2020 14:09:56
	System	15 Nov 2020 14:09:56

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '14 Nov 2020 12:00'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '15 Nov 2020 11:59'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
Data entry locked.	System	12 Nov 2020 14:07:00
User entered 'Day 4'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:51:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-15T12:32:15', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '1ec55abb-f1ce-4e36-adb3-07e65236f6b4' User entered 'Yes (Y)'	System	15 Nov 2020 17:32:36
	System	15 Nov 2020 17:32:36

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:51:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-15T12:32:24', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '1ec55abb-f1ce-4e36-adb3-07e65236f6b4' User entered '97.6'	System	15 Nov 2020 17:32:36
	System	15 Nov 2020 17:32:36

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-15T12:32:27', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '1ec55abb-f1ce-4e36-adb3-07e65236f6b4'	System	15 Nov 2020 17:32:36
User entered 'No (N)'	System	15 Nov 2020 17:32:36

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-15T12:32:31', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '1ec55abb-f1ce-4e36-adb3-07e65236f6b4' User entered '15 Nov 2020 12:32'	System	15 Nov 2020 17:32:36
	System	15 Nov 2020 17:32:36

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '15 Nov 2020 12:00'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '16 Nov 2020 11:59'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
Data entry locked.	System	12 Nov 2020 14:07:00
User entered 'Day 5'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:51:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-16T12:00:40', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '9bb2f292-817b-41c1-b34a-0a0426cd54a9' User entered 'No (N)'	System	16 Nov 2020 17:01:03
	System	16 Nov 2020 17:01:03

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-16T12:00:42', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '9bb2f292-817b-41c1-b34a-0a0426cd54a9' User entered 'No (N)'	System	16 Nov 2020 17:01:03
	System	16 Nov 2020 17:01:03

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-16T12:00:46', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '9bb2f292-817b-41c1-b34a-0a0426cd54a9' User entered '16 Nov 2020 12:00'	System	16 Nov 2020 17:01:03
	System	16 Nov 2020 17:01:03

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '16 Nov 2020 12:00'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '17 Nov 2020 11:59'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
Data entry locked.	System	12 Nov 2020 14:07:00
User entered 'Day 6'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:51:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-17T15:38:38', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'c26c2f01-6a98-43ca-b98b-6b8ee9455e53' User entered 'Yes (Y)'	System	17 Nov 2020 20:38:52
	System	17 Nov 2020 20:38:52

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:51:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-17T15:38:44', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'c26c2f01-6a98-43ca-b98b-6b8ee9455e53' User entered '97.3'	System	17 Nov 2020 20:38:52
	System	17 Nov 2020 20:38:52

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-17T15:38:47', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'c26c2f01-6a98-43ca-b98b-6b8ee9455e53'	System	17 Nov 2020 20:38:52
User entered 'No (N)'	System	17 Nov 2020 20:38:52

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-17T15:38:50', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'c26c2f01-6a98-43ca-b98b-6b8ee9455e53' User entered '17 Nov 2020 15:38'	System	17 Nov 2020 20:38:52
	System	17 Nov 2020 20:38:52

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '17 Nov 2020 12:00'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '18 Nov 2020 11:59'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
Data entry locked.	System	12 Nov 2020 14:07:00
User entered 'Day 7'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:51:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-18T15:50:21', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'ee841173-e1d7-4097-b3c9-d689de8160c6' User entered 'Yes (Y)'	System	18 Nov 2020 20:50:41
	System	18 Nov 2020 20:50:41

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:51:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-18T15:50:33', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'ee841173-e1d7-4097-b3c9-d689de8160c6' User entered '97.8'	System	18 Nov 2020 20:50:41
	System	18 Nov 2020 20:50:41

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-18T15:50:36', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'ee841173-e1d7-4097-b3c9-d689de8160c6' User entered 'No (N)'	System	18 Nov 2020 20:50:41
	System	18 Nov 2020 20:50:41

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-18T15:50:39', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'ee841173-e1d7-4097-b3c9-d689de8160c6'	System	18 Nov 2020 20:50:41
User entered '18 Nov 2020 15:50'	System	18 Nov 2020 20:50:41

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '18 Nov 2020 12:00'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '19 Nov 2020 11:59'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
Data entry locked.	System	12 Nov 2020 14:07:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:51:52

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 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-12T09:25:28', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '044c0f0c-d046-4d10-9671-58ef7dec72f2'	System	12 Nov 2020 14:32:27
User entered 'None (1)'	System	12 Nov 2020 14:32:27

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:51:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-12T09:25:30', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '044c0f0c-d046-4d10-9671-58ef7dec72f2'	System	12 Nov 2020 14:32:27
User entered 'No (N)'	System	12 Nov 2020 14:32:27

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-12T09:32:16', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '044c0f0c-d046-4d10-9671-58ef7dec72f2'	System	12 Nov 2020 14:32:27
User entered 'No (N)'	System	12 Nov 2020 14:32:27

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:51:52

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 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-12T09:32:19', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '044c0f0c-d046-4d10-9671-58ef7dec72f2'	System	12 Nov 2020 14:32:27
User entered 'None (1)'	System	12 Nov 2020 14:32:27

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-12T09:32:23', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '044c0f0c-d046-4d10-9671-58ef7dec72f2'	System	12 Nov 2020 14:32:27
User entered '12 Nov 2020 09:32'	System	12 Nov 2020 14:32:27

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '12 Nov 2020 09:19'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '12 Nov 2020 11:49'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
Data entry locked.	System	12 Nov 2020 14:07:00
User entered 'Day 1, after vaccination (at home)'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:51:52

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 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-12T13:09:12', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '88f8829f-3c19-417c-9f43-e310ab797d05'	System	12 Nov 2020 18:09:25
User entered 'None (1)'	System	12 Nov 2020 18:09:25

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:51:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-12T13:09:14', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '88f8829f-3c19-417c-9f43-e310ab797d05'	System	12 Nov 2020 18:09:25
User entered 'No (N)'	System	12 Nov 2020 18:09:25

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-12T13:09:16', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '88f8829f-3c19-417c-9f43-e310ab797d05'	System	12 Nov 2020 18:09:25
User entered 'No (N)'	System	12 Nov 2020 18:09:25

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:51:52

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 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-12T13:09:19', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '88f8829f-3c19-417c-9f43-e310ab797d05'	System	12 Nov 2020 18:09:25
User entered 'None (1)'	System	12 Nov 2020 18:09:25

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-12T13:09:22', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '88f8829f-3c19-417c-9f43-e310ab797d05'	System	12 Nov 2020 18:09:25
User entered '12 Nov 2020 13:09'	System	12 Nov 2020 18:09:25

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '12 Nov 2020 12:44'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '13 Nov 2020 11:59'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
Data entry locked.	System	12 Nov 2020 14:07:00
User entered 'Day 2'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:51:52

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 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-14T07:27:00', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'd92b4b0f-4d9a-47ff-92d8-501bb2fe3ed2'	System	15 Nov 2020 14:06:52
User entered 'None (1)'	System	15 Nov 2020 14:06:52

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:51:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-14T07:27:02', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'd92b4b0f-4d9a-47ff-92d8-501bb2fe3ed2'	System	15 Nov 2020 14:06:52
User entered 'No (N)'	System	15 Nov 2020 14:06:52

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-14T07:27:04', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'd92b4b0f-4d9a-47ff-92d8-501bb2fe3ed2'	System	15 Nov 2020 14:06:52
User entered 'No (N)'	System	15 Nov 2020 14:06:52

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:51:52

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 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-14T07:27:07', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'd92b4b0f-4d9a-47ff-92d8-501bb2fe3ed2'	System	15 Nov 2020 14:06:52
User entered 'None (1)'	System	15 Nov 2020 14:06:52

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-14T07:27:09', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'd92b4b0f-4d9a-47ff-92d8-501bb2fe3ed2'	System	15 Nov 2020 14:06:52
User entered '14 Nov 2020 07:27'	System	15 Nov 2020 14:06:52

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '13 Nov 2020 12:00'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '14 Nov 2020 11:59'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
Data entry locked.	System	12 Nov 2020 14:07:00
User entered 'Day 3'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:51:52

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 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-15T09:09:58', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'a8dbf857-ef6e-478c-910d-faea0d2aa326'	System	15 Nov 2020 14:10:27
User entered 'None (1)'	System	15 Nov 2020 14:10:27

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:51:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-15T09:10:02', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'a8dbf857-ef6e-478c-910d-faea0d2aa326'	System	15 Nov 2020 14:10:27
User entered 'No (N)'	System	15 Nov 2020 14:10:27

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-15T09:10:07', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'a8dbf857-ef6e-478c-910d-faea0d2aa326'	System	15 Nov 2020 14:10:27
User entered 'No (N)'	System	15 Nov 2020 14:10:27

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:51:52

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 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-15T09:10:17', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'a8dbf857-ef6e-478c-910d-faea0d2aa326'	System	15 Nov 2020 14:10:27
User entered 'None (1)'	System	15 Nov 2020 14:10:27

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-15T09:10:24', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'a8dbf857-ef6e-478c-910d-faea0d2aa326' User entered '15 Nov 2020 09:10'	System	15 Nov 2020 14:10:27
	System	15 Nov 2020 14:10:27

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '14 Nov 2020 12:00'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '15 Nov 2020 11:59'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
Data entry locked.	System	12 Nov 2020 14:07:00
User entered 'Day 4'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:51:52

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 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-15T12:32:33', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'dedebbc5-c6cd-4cff-b8dc-9c7e0e6e6204' User entered 'None (1)'	System	15 Nov 2020 17:32:46
	System	15 Nov 2020 17:32:46

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:51:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-15T12:32:36', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'dedebbc5-c6cd-4cff-b8dc-9c7e0e6e6204' User entered 'No (N)'	System	15 Nov 2020 17:32:46
	System	15 Nov 2020 17:32:46

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-15T12:32:37', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'dedebbc5-c6cd-4cff-b8dc-9c7e0e6e6204' User entered 'No (N)'	System	15 Nov 2020 17:32:46
	System	15 Nov 2020 17:32:46

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:51:52

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 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-15T12:32:39', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'dedebbc5-c6cd-4cff-b8dc-9c7e0e6e6204' User entered 'None (1)'	System	15 Nov 2020 17:32:46
	System	15 Nov 2020 17:32:46

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-15T12:32:42', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'dedebbc5-c6cd-4cff-b8dc-9c7e0e6e6204' User entered '15 Nov 2020 12:32'	System	15 Nov 2020 17:32:46
	System	15 Nov 2020 17:32:46

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '15 Nov 2020 12:00'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '16 Nov 2020 11:59'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
Data entry locked.	System	12 Nov 2020 14:07:00
User entered 'Day 5'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:51:52

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 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-16T12:00:49', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '984608e5-e14a-4031-972f-474d32321f42'	System	16 Nov 2020 17:01:15
User entered 'None (1)'	System	16 Nov 2020 17:01:15

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:51:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-16T12:00:51', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '984608e5-e14a-4031-972f-474d32321f42'	System	16 Nov 2020 17:01:15
User entered 'No (N)'	System	16 Nov 2020 17:01:15

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-16T12:00:52', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '984608e5-e14a-4031-972f-474d32321f42' User entered 'No (N)'	System	16 Nov 2020 17:01:15
	System	16 Nov 2020 17:01:15

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:51:52

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 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-16T12:00:54', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '984608e5-e14a-4031-972f-474d32321f42'	System	16 Nov 2020 17:01:15
User entered 'None (1)'	System	16 Nov 2020 17:01:15

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-16T12:00:57', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '984608e5-e14a-4031-972f-474d32321f42'	System	16 Nov 2020 17:01:15
User entered '16 Nov 2020 12:00'	System	16 Nov 2020 17:01:15

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '16 Nov 2020 12:00'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '17 Nov 2020 11:59'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
Data entry locked.	System	12 Nov 2020 14:07:00
User entered 'Day 6'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:51:52

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 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-17T15:38:55', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'bd8ea669-9594-45d0-aff1-983e1511a149'	System	17 Nov 2020 20:39:10
User entered 'None (1)'	System	17 Nov 2020 20:39:10

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:51:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-17T15:38:58', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'bd8ea669-9594-45d0-aff1-983e1511a149'	System	17 Nov 2020 20:39:10
User entered 'No (N)'	System	17 Nov 2020 20:39:10

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-17T15:39:00', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'bd8ea669-9594-45d0-aff1-983e1511a149'	System	17 Nov 2020 20:39:10
User entered 'No (N)'	System	17 Nov 2020 20:39:10

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:51:52

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 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-17T15:39:01', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'bd8ea669-9594-45d0-aff1-983e1511a149'	System	17 Nov 2020 20:39:10
User entered 'None (1)'	System	17 Nov 2020 20:39:10

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-17T15:39:06', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'bd8ea669-9594-45d0-aff1-983e1511a149'	System	17 Nov 2020 20:39:10
User entered '17 Nov 2020 15:39'	System	17 Nov 2020 20:39:10

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '17 Nov 2020 12:00'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '18 Nov 2020 11:59'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
Data entry locked.	System	12 Nov 2020 14:07:00
User entered 'Day 7'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:51:52

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 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-18T15:50:55', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '6f46c964-eb9d-47ac-9d2b-7caff638fa4'	System	18 Nov 2020 20:51:09
User entered 'None (1)'	System	18 Nov 2020 20:51:09

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:51:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-18T15:50:58', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '6f46c964-eb9d-47ac-9d2b-7caff638fa4'	System	18 Nov 2020 20:51:09
User entered 'No (N)'	System	18 Nov 2020 20:51:09

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-18T15:51:01', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '6f46c964-eb9d-47ac-9d2b-7caffe638fa4'	System	18 Nov 2020 20:51:09
User entered 'No (N)'	System	18 Nov 2020 20:51:09

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:51:52

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 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-18T15:51:04', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '6f46c964-eb9d-47ac-9d2b-7caff638fa4'	System	18 Nov 2020 20:51:09
User entered 'None (1)'	System	18 Nov 2020 20:51:09

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-18T15:51:06', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '6f46c964-eb9d-47ac-9d2b-7caff638fa4' User entered '18 Nov 2020 15:51'	System	18 Nov 2020 20:51:09
	System	18 Nov 2020 20:51:09

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '18 Nov 2020 12:00'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '19 Nov 2020 11:59'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
Data entry locked.	System	12 Nov 2020 14:07:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:51:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-12T09:32:29', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '4eeb0693-b777-4fb0-b71b-9d2e9aafe98c' User entered 'None (0)'	System	12 Nov 2020 14:33:41
	System	12 Nov 2020 14:33:41

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:51:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-12T09:32:31', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '4eeb0693-b777-4fb0-b71b-9d2e9aafe98c' User entered 'None (0)'	System	12 Nov 2020 14:33:41
	System	12 Nov 2020 14:33:41

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:51:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-12T09:32:33', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '4eeb0693-b777-4fb0-b71b-9d2e9aafe98c' User entered 'None (0)'	System	12 Nov 2020 14:33:41
	System	12 Nov 2020 14:33:41

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:51:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-12T09:32:53', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '4eeb0693-b777-4fb0-b71b-9d2e9aafe98c' User entered 'None (0)'	System	12 Nov 2020 14:33:41
	System	12 Nov 2020 14:33:41

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:51:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-12T09:32:58', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '4eeb0693-b777-4fb0-b71b-9d2e9aafe98c' User entered 'None (0)'	System	12 Nov 2020 14:33:41
	System	12 Nov 2020 14:33:41

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:51:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-12T09:33:00', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '4eeb0693-b777-4fb0-b71b-9d2e9aafe98c' User entered 'None (0)'	System	12 Nov 2020 14:33:41
	System	12 Nov 2020 14:33:41

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:51:52

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 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-12T09:33:30', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '4eeb0693-b777-4fb0-b71b-9d2e9aafe98c' User entered 'No (N)'	System	12 Nov 2020 14:33:41
	System	12 Nov 2020 14:33:41

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:51:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-12T09:33:37', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '4eeb0693-b777-4fb0-b71b-9d2e9aafe98c' User entered '12 Nov 2020 09:33'	System	12 Nov 2020 14:33:41
	System	12 Nov 2020 14:33:41

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '12 Nov 2020 09:19'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '12 Nov 2020 11:49'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
Data entry locked.	System	12 Nov 2020 14:07:00
User entered 'Day 1, after vaccination (at home)'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:51:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-12T13:09:26', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '6c8a6c60-cf1e-4acb-82fd-f4044ae0f34d' User entered 'None (0)'	System	12 Nov 2020 18:09:45
	System	12 Nov 2020 18:09:45

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:51:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-12T13:09:28', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '6c8a6c60-cf1e-4acb-82fd-f4044ae0f34d' User entered 'None (0)'	System	12 Nov 2020 18:09:45
	System	12 Nov 2020 18:09:45

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:51:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-12T13:09:29', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '6c8a6c60-cf1e-4acb-82fd-f4044ae0f34d' User entered 'None (0)'	System	12 Nov 2020 18:09:45
	System	12 Nov 2020 18:09:45

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:51:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-12T13:09:31', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '6c8a6c60-cf1e-4acb-82fd-f4044ae0f34d' User entered 'None (0)'	System	12 Nov 2020 18:09:45
	System	12 Nov 2020 18:09:45

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:51:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-12T13:09:33', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '6c8a6c60-cf1e-4acb-82fd-f4044ae0f34d' User entered 'None (0)'	System	12 Nov 2020 18:09:45
	System	12 Nov 2020 18:09:45

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:51:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-12T13:09:35', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '6c8a6c60-cf1e-4acb-82fd-f4044ae0f34d' User entered 'None (0)'	System	12 Nov 2020 18:09:45
	System	12 Nov 2020 18:09:45

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:51:52

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 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-12T13:09:37', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '6c8a6c60-cf1e-4acb-82fd-f4044ae0f34d' User entered 'No (N)'	System	12 Nov 2020 18:09:45
	System	12 Nov 2020 18:09:45

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:51:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-12T13:09:40', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '6c8a6c60-cf1e-4acb-82fd-f4044ae0f34d' User entered '12 Nov 2020 13:09'	System	12 Nov 2020 18:09:45
	System	12 Nov 2020 18:09:45

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '12 Nov 2020 12:44'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '13 Nov 2020 11:59'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
Data entry locked.	System	12 Nov 2020 14:07:00
User entered 'Day 2'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:51:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-14T07:27:12', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '90d0f834-0bd1-4171-8ecd-95e0b125d90a' User entered 'None (0)'	System	15 Nov 2020 14:06:53
	System	15 Nov 2020 14:06:53

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:51:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-14T07:27:14', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '90d0f834-0bd1-4171-8ecd-95e0b125d90a' User entered 'None (0)'	System	15 Nov 2020 14:06:53
	System	15 Nov 2020 14:06:53

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:51:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-14T07:27:15', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '90d0f834-0bd1-4171-8ecd-95e0b125d90a' User entered 'None (0)'	System	15 Nov 2020 14:06:53
	System	15 Nov 2020 14:06:53

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:51:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-14T07:27:16', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '90d0f834-0bd1-4171-8ecd-95e0b125d90a' User entered 'None (0)'	System	15 Nov 2020 14:06:53
	System	15 Nov 2020 14:06:53

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:51:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-14T07:27:18', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '90d0f834-0bd1-4171-8ecd-95e0b125d90a' User entered 'None (0)'	System	15 Nov 2020 14:06:53
	System	15 Nov 2020 14:06:53

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:51:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-14T07:27:19', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '90d0f834-0bd1-4171-8ecd-95e0b125d90a' User entered 'None (0)'	System	15 Nov 2020 14:06:53
	System	15 Nov 2020 14:06:53

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:51:52

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 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-14T07:27:21', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '90d0f834-0bd1-4171-8ecd-95e0b125d90a' User entered 'No (N)'	System	15 Nov 2020 14:06:53
	System	15 Nov 2020 14:06:53

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:51:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-14T07:27:23', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '90d0f834-0bd1-4171-8ecd-95e0b125d90a' User entered '14 Nov 2020 07:27'	System	15 Nov 2020 14:06:53
	System	15 Nov 2020 14:06:53

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '13 Nov 2020 12:00'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '14 Nov 2020 11:59'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
Data entry locked.	System	12 Nov 2020 14:07:00
User entered 'Day 3'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:51:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-15T09:10:27', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '4ea1ff2e-2657-4514-8403-6fcda9de8810' User entered 'None (0)'	System	15 Nov 2020 14:10:43
	System	15 Nov 2020 14:10:43

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:51:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-15T09:10:29', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '4ea1ff2e-2657-4514-8403-6fcda9de8810' User entered 'None (0)'	System	15 Nov 2020 14:10:43
	System	15 Nov 2020 14:10:43

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:51:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-15T09:10:31', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '4ea1ff2e-2657-4514-8403-6fcda9de8810' User entered 'None (0)'	System	15 Nov 2020 14:10:43
	System	15 Nov 2020 14:10:43

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:51:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-15T09:10:33', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '4ea1ff2e-2657-4514-8403-6fcda9de8810' User entered 'None (0)'	System	15 Nov 2020 14:10:43
	System	15 Nov 2020 14:10:43

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:51:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-15T09:10:34', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '4ea1ff2e-2657-4514-8403-6fcda9de8810' User entered 'None (0)'	System	15 Nov 2020 14:10:43
	System	15 Nov 2020 14:10:43

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:51:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-15T09:10:36', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '4ea1ff2e-2657-4514-8403-6fcda9de8810' User entered 'None (0)'	System	15 Nov 2020 14:10:43
	System	15 Nov 2020 14:10:43

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:51:52

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 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-15T09:10:38', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '4ea1ff2e-2657-4514-8403-6fcda9de8810' User entered 'No (N)'	System	15 Nov 2020 14:10:43
	System	15 Nov 2020 14:10:43

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:51:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-15T09:10:40', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '4ea1ff2e-2657-4514-8403-6fcda9de8810'	System	15 Nov 2020 14:10:43
User entered '15 Nov 2020 09:10'	System	15 Nov 2020 14:10:43

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '14 Nov 2020 12:00'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '15 Nov 2020 11:59'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
Data entry locked.	System	12 Nov 2020 14:07:00
User entered 'Day 4'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:51:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-15T12:32:44', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'c61661f5-81d7-49bd-9479-b897f81e3b8f' User entered 'None (0)'	System	15 Nov 2020 17:32:59
	System	15 Nov 2020 17:32:59

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:51:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-15T12:32:46', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'c61661f5-81d7-49bd-9479-b897f81e3b8f' User entered 'None (0)'	System	15 Nov 2020 17:32:59
	System	15 Nov 2020 17:32:59

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:51:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-15T12:32:47', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'c61661f5-81d7-49bd-9479-b897f81e3b8f' User entered 'None (0)'	System	15 Nov 2020 17:32:59
	System	15 Nov 2020 17:32:59

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:51:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-15T12:32:49', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'c61661f5-81d7-49bd-9479-b897f81e3b8f' User entered 'None (0)'	System	15 Nov 2020 17:32:59
	System	15 Nov 2020 17:32:59

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:51:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-15T12:32:50', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'c61661f5-81d7-49bd-9479-b897f81e3b8f' User entered 'None (0)'	System	15 Nov 2020 17:32:59
	System	15 Nov 2020 17:32:59

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:51:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-15T12:32:51', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'c61661f5-81d7-49bd-9479-b897f81e3b8f' User entered 'None (0)'	System	15 Nov 2020 17:32:59
	System	15 Nov 2020 17:32:59

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:51:52

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 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-15T12:32:54', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'c61661f5-81d7-49bd-9479-b897f81e3b8f' User entered 'No (N)'	System	15 Nov 2020 17:32:59
	System	15 Nov 2020 17:32:59

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:51:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-15T12:32:56', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'c61661f5-81d7-49bd-9479-b897f81e3b8f' User entered '15 Nov 2020 12:32'	System	15 Nov 2020 17:32:59
	System	15 Nov 2020 17:32:59

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '15 Nov 2020 12:00'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '16 Nov 2020 11:59'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
Data entry locked.	System	12 Nov 2020 14:07:00
User entered 'Day 5'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:51:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-16T12:00:59', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '5cb6eaa1-38e9-450b-818a-a261545f8942' User entered 'None (0)'	System	16 Nov 2020 17:01:44
	System	16 Nov 2020 17:01:44

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:51:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-16T12:01:02', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '5cb6eaa1-38e9-450b-818a-a261545f8942' User entered 'None (0)'	System	16 Nov 2020 17:01:44
	System	16 Nov 2020 17:01:44

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:51:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-16T12:01:03', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '5cb6eaa1-38e9-450b-818a-a261545f8942' User entered 'None (0)'	System	16 Nov 2020 17:01:44
	System	16 Nov 2020 17:01:44

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:51:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-16T12:01:04', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '5cb6eaa1-38e9-450b-818a-a261545f8942' User entered 'None (0)'	System	16 Nov 2020 17:01:44
	System	16 Nov 2020 17:01:44

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:51:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-16T12:01:05', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '5cb6eaa1-38e9-450b-818a-a261545f8942' User entered 'None (0)'	System	16 Nov 2020 17:01:44
	System	16 Nov 2020 17:01:44

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:51:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-16T12:01:07', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '5cb6eaa1-38e9-450b-818a-a261545f8942' User entered 'None (0)'	System	16 Nov 2020 17:01:44
	System	16 Nov 2020 17:01:44

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:51:52

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 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-16T12:01:09', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '5cb6eaa1-38e9-450b-818a-a261545f8942' User entered 'No (N)'	System	16 Nov 2020 17:01:44
	System	16 Nov 2020 17:01:44

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:51:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-16T12:01:11', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '5cb6eaa1-38e9-450b-818a-a261545f8942' User entered '16 Nov 2020 12:01'	System	16 Nov 2020 17:01:44
	System	16 Nov 2020 17:01:44

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '16 Nov 2020 12:00'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '17 Nov 2020 11:59'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
Data entry locked.	System	12 Nov 2020 14:07:00
User entered 'Day 6'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:51:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-17T15:39:09', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '2fd346db-7f21-4542-a68e-f1b26f1aa688' User entered 'None (0)'	System	17 Nov 2020 20:39:30
	System	17 Nov 2020 20:39:30

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:51:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-17T15:39:11', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '2fd346db-7f21-4542-a68e-f1b26f1aa688' User entered 'None (0)'	System	17 Nov 2020 20:39:30
	System	17 Nov 2020 20:39:30

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:51:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-17T15:39:13', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '2fd346db-7f21-4542-a68e-f1b26f1aa688' User entered 'None (0)'	System	17 Nov 2020 20:39:30
	System	17 Nov 2020 20:39:30

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:51:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-17T15:39:15', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '2fd346db-7f21-4542-a68e-f1b26f1aa688' User entered 'None (0)'	System	17 Nov 2020 20:39:30
	System	17 Nov 2020 20:39:30

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:51:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-17T15:39:16', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '2fd346db-7f21-4542-a68e-f1b26f1aa688' User entered 'None (0)'	System	17 Nov 2020 20:39:30
	System	17 Nov 2020 20:39:30

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:51:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-17T15:39:23', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '2fd346db-7f21-4542-a68e-f1b26f1aa688' User entered 'None (0)'	System	17 Nov 2020 20:39:30
	System	17 Nov 2020 20:39:30

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:51:52

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 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-17T15:39:25', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '2fd346db-7f21-4542-a68e-f1b26f1aa688'	System	17 Nov 2020 20:39:30
User entered 'No (N)'	System	17 Nov 2020 20:39:30

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:51:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-17T15:39:28', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '2fd346db-7f21-4542-a68e-f1b26f1aa688' User entered '17 Nov 2020 15:39'	System	17 Nov 2020 20:39:30
	System	17 Nov 2020 20:39:30

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '17 Nov 2020 12:00'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '18 Nov 2020 11:59'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
Data entry locked.	System	12 Nov 2020 14:07:00
User entered 'Day 7'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:51:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-18T15:51:09', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '56295894-6ce3-4093-bbf9-a0f0d4579e98' User entered 'None (0)'	System	18 Nov 2020 20:51:27
	System	18 Nov 2020 20:51:27

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:51:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-18T15:51:11', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '56295894-6ce3-4093-bbf9-a0f0d4579e98' User entered 'None (0)'	System	18 Nov 2020 20:51:27
	System	18 Nov 2020 20:51:27

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:51:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-18T15:51:13', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '56295894-6ce3-4093-bbf9-a0f0d4579e98' User entered 'None (0)'	System	18 Nov 2020 20:51:27
	System	18 Nov 2020 20:51:27

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:51:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-18T15:51:15', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '56295894-6ce3-4093-bbf9-a0f0d4579e98' User entered 'None (0)'	System	18 Nov 2020 20:51:27
	System	18 Nov 2020 20:51:27

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:51:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-18T15:51:16', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '56295894-6ce3-4093-bbf9-a0f0d4579e98' User entered 'None (0)'	System	18 Nov 2020 20:51:27
	System	18 Nov 2020 20:51:27

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:51:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-18T15:51:18', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '56295894-6ce3-4093-bbf9-a0f0d4579e98'	System	18 Nov 2020 20:51:27
User entered 'None (0)'	System	18 Nov 2020 20:51:27

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:51:52

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 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-18T15:51:21', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '56295894-6ce3-4093-bbf9-a0f0d4579e98'	System	18 Nov 2020 20:51:27
User entered 'No (N)'	System	18 Nov 2020 20:51:27

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:51:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-11-18T15:51:24', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '56295894-6ce3-4093-bbf9-a0f0d4579e98' User entered '18 Nov 2020 15:51'	System	18 Nov 2020 20:51:27
	System	18 Nov 2020 20:51:27

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '18 Nov 2020 12:00'	System	12 Nov 2020 14:07:00

US3482286

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:36
User entered '19 Nov 2020 11:59'	System	12 Nov 2020 14:07:00

US3482286

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:51:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered 'Yes (Y)'	(b) (4) Amy Anderson (b) (4)	19 Nov 2020 14:16:39

US3482286

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered '19 Nov 2020'	(b) (4) Amy Anderson (b) (4)	19 Nov 2020 14:16:39

US3482286

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:51:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Amy Anderson (b) (4)	19 Nov 2020 14:16:39

US3482286

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:51:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered empty.	(b) (4) Amy Anderson (b) (4)	19 Nov 2020 14:16:39

US3482286

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:51:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered 'Yes (Y)'	(b) (4) Amy Anderson (b) (4)	19 Nov 2020 14:16:46

US3482286

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:51:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User entered 'I'	System	19 Nov 2020 14:16:46

US3482286

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:51:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered 'Yes (Y)'	(b) (4) Amy Anderson (b) (4)	27 Nov 2020 16:58:25

US3482286

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered '27 Nov 2020'	(b) (4) Amy Anderson (b) (4)	27 Nov 2020 16:58:25

US3482286

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:51:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Amy Anderson (b) (4)	27 Nov 2020 16:58:25

US3482286

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:51:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered empty.	(b) (4) Amy Anderson (b) (4)	27 Nov 2020 16:58:25

US3482286

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:51:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered 'Yes (Y)'	(b) (4) Amy Anderson (b) (4)	27 Nov 2020 16:58:30

US3482286

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:51:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User entered 'I'	System	27 Nov 2020 16:58:30

US3482286

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:51:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered 'Yes (Y)'	(b) (4) Amy Anderson (b) (4)	03 Dec 2020 16:28:27

US3482286

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered '03 Dec 2020'	(b) (4) Amy Anderson (b) (4)	03 Dec 2020 16:28:27

US3482286

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:51:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Amy Anderson (b) (4)	03 Dec 2020 16:28:27

US3482286

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:51:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered empty.	(b) (4) Amy Anderson (b) (4)	03 Dec 2020 16:28:27

US3482286

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:51:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered 'Yes (Y)'	(b) (4) Amy Anderson (b) (4)	03 Dec 2020 16:28:32

US3482286

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:51:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User entered 'I'	System	03 Dec 2020 16:28:32

US3482286

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:51:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered 'Yes (Y)'	(b) (4) Amy Anderson (b) (4)	10 Dec 2020 14:43:52

US3482286

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered '10 Dec 2020'	(b) (4) Amy Anderson (b) (4)	10 Dec 2020 14:43:52

US3482286

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:51:52

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered 'Clinic (Clinic)'	(b) (4) Amy Anderson (b) (4)	10 Dec 2020 14:43:52

US3482286

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:51:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User entered 'VISIT3'	System	10 Dec 2020 14:43:52

US3482286

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered 'No (N)'	(b) (4) Amy Anderson (b) (4)	10 Dec 2020 14:44:02

US3482286

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered empty.	(b) (4) Amy Anderson (b) (4)	10 Dec 2020 14:44:02

US3482286

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered empty.	(b) (4) Amy Anderson (b) (4)	10 Dec 2020 14:44:02

US3482286

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User entered empty.	System	10 Dec 2020 14:44:02

US3482286

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered empty.	(b) (4) Amy Anderson (b) (4)	10 Dec 2020 14:44:02

US3482286

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered empty.	(b) (4) Amy Anderson (b) (4)	10 Dec 2020 14:44:02

US3482286

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered empty.	(b) (4) Amy Anderson (b) (4)	10 Dec 2020 14:44:02

US3482286

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered empty.	(b) (4) Amy Anderson (b) (4)	10 Dec 2020 14:44:02

US3482286

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User entered empty.	System	10 Dec 2020 14:44:02

US3482286

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered empty.	(b) (4) Amy Anderson (b) (4)	10 Dec 2020 14:44:02

US3482286

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User entered empty.	System	10 Dec 2020 14:44:02

US3482286

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered empty.	(b) (4) Amy Anderson (b) (4)	10 Dec 2020 14:44:02

US3482286

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User entered empty.	System	10 Dec 2020 14:44:02

US3482286

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered empty.	(b) (4) Amy Anderson (b) (4)	10 Dec 2020 14:44:02

US3482286

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User entered empty.	System	10 Dec 2020 14:44:02

US3482286

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09

US3482286

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09

US3482286

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:51:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered 'No (N)'	(b) (4) Amy Anderson (b) (4)	10 Dec 2020 14:44:09

US3482286

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:51:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered empty.	(b) (4) Amy Anderson (b) (4)	10 Dec 2020 14:44:09

US3482286

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:51:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered 'Yes (Y)'	(b) (4) Amy Anderson (b) (4)	10 Dec 2020 14:44:27

US3482286

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:51:52

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered '10 Dec 2020'	(b) (4) Amy Anderson (b) (4)	10 Dec 2020 14:44:27

US3482286

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:51:52

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered '09:20'	(b) (4) Amy Anderson (b) (4)	10 Dec 2020 14:44:27

US3482286

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:51:52

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User entered '10 Dec 2020 09:20'	System	10 Dec 2020 14:44:27

US3482286

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:51:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:17
User entered 'Yes (Y)'	(b) (4) Amy Anderson (b) (4)	10 Dec 2020 14:44:32

US3482286

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:51:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:09
User entered 'I'	System	10 Dec 2020 14:44:32

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[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 (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-12-14T08:55:02', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '2f10ca1b-6664-4fef-b24d-a18d7794a272'	System	14 Dec 2020 13:55:11
User entered 'No (N)'	System	14 Dec 2020 13:55:11

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

Have you been exposed to someone with 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 (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-12-14T08:55:05', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '2f10ca1b-6664-4fef-b24d-a18d7794a272'	System	14 Dec 2020 13:55:11
User entered 'No (N)'	System	14 Dec 2020 13:55:11

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-12-14T08:55:08', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '2f10ca1b-6664-4fef-b24d-a18d7794a272' User entered '14 Dec 2020 08:55:08'	System	14 Dec 2020 13:55:11
	System	14 Dec 2020 13:55:11

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '10 Dec 2020 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '14 Dec 2020 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[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 (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-12-17T00:02:14', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '98207e18-7105-4b74-af26-ac48a0ce01ee' User entered 'No (N)'	System	17 Dec 2020 05:02:41
	System	17 Dec 2020 05:02:41

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

Have you been exposed to someone with 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 (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-12-17T00:02:18', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '98207e18-7105-4b74-af26-ac48a0ce01ee' User entered 'No (N)'	System	17 Dec 2020 05:02:41
	System	17 Dec 2020 05:02:41

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-12-17T00:02:24', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '98207e18-7105-4b74-af26-ac48a0ce01ee' User entered '17 Dec 2020 00:02:24'	System	17 Dec 2020 05:02:41
	System	17 Dec 2020 05:02:41

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '17 Dec 2020 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '21 Dec 2020 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[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 (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-12-26T12:29:50', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '6454b322-654f-4e2d-b8c6-4eb676146e03' User entered 'No (N)'	System	26 Dec 2020 17:29:58
	System	26 Dec 2020 17:29:58

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

Have you been exposed to someone with 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 (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-12-26T12:29:52', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '6454b322-654f-4e2d-b8c6-4eb676146e03' User entered 'No (N)'	System	26 Dec 2020 17:29:58
	System	26 Dec 2020 17:29:58

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2020-12-26T12:29:56', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '6454b322-654f-4e2d-b8c6-4eb676146e03' User entered '26 Dec 2020 12:29:56'	System	26 Dec 2020 17:29:58
	System	26 Dec 2020 17:29:58

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '24 Dec 2020 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '28 Dec 2020 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[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 (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-01-02T15:49:48', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '03f8c86f-a9bb-4481-99c0-0049c19cae4a' User entered 'No (N)'	System	02 Jan 2021 20:49:58
	System	02 Jan 2021 20:49:58

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

Have you been exposed to someone with 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 (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-01-02T15:49:52', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '03f8c86f-a9bb-4481-99c0-0049c19cae4a'	System	02 Jan 2021 20:49:58
User entered 'No (N)'	System	02 Jan 2021 20:49:58

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-01-02T15:49:55', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '03f8c86f-a9bb-4481-99c0-0049c19cae4a' User entered '02 Jan 2021 15:49:55'	System	02 Jan 2021 20:49:58
	System	02 Jan 2021 20:49:58

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '31 Dec 2020 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '04 Jan 2021 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[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 (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-01-07T08:15:25', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'fd7ddf47-99fa-4337-a78f-557d3fcc53c9' User entered 'Yes (Y)'	System	07 Jan 2021 13:16:43
	System	07 Jan 2021 13:16:43

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

Have you been exposed to someone with 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 (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-01-07T08:15:28', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'fd7ddf47-99fa-4337-a78f-557d3fcc53c9'	System	07 Jan 2021 13:16:43
User entered 'No (N)'	System	07 Jan 2021 13:16:43

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[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 (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-01-07T08:15:40', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'fd7ddf47-99fa-4337-a78f-557d3fcc53c9' User entered 'Yes (Y)'	System	07 Jan 2021 13:16:43
	System	07 Jan 2021 13:16:43

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-01-07T08:16:10', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'fd7ddf47-99fa-4337-a78f-557d3fcc53c9' User entered '0'	System	07 Jan 2021 13:16:43

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-01-07T08:16:10', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'fd7ddf47-99fa-4337-a78f-557d3fcc53c9' User entered '0'	System	07 Jan 2021 13:16:43

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-01-07T08:16:10', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'fd7ddf47-99fa-4337-a78f-557d3fcc53c9'	System	07 Jan 2021 13:16:43
User entered '1'	System	07 Jan 2021 13:16:43

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-01-07T08:16:10', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'fd7ddf47-99fa-4337-a78f-557d3fcc53c9' User entered '0'	System	07 Jan 2021 13:16:43
	System	07 Jan 2021 13:16:43

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-01-07T08:16:10', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'fd7ddf47-99fa-4337-a78f-557d3fcc53c9'	System	07 Jan 2021 13:16:43
User entered '0'	System	07 Jan 2021 13:16:43

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-01-07T08:16:10', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'fd7ddf47-99fa-4337-a78f-557d3fcc53c9' User entered '0'	System	07 Jan 2021 13:16:43

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-01-07T08:16:10', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'fd7ddf47-99fa-4337-a78f-557d3fcc53c9'	System	07 Jan 2021 13:16:43
User entered '0'	System	07 Jan 2021 13:16:43

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-01-07T08:16:10', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'fd7ddf47-99fa-4337-a78f-557d3fcc53c9'	System	07 Jan 2021 13:16:43
User entered '1'	System	07 Jan 2021 13:16:43

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-01-07T08:16:10', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'fd7ddf47-99fa-4337-a78f-557d3fcc53c9' User entered '1'	System	07 Jan 2021 13:16:43

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-01-07T08:16:10', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'fd7ddf47-99fa-4337-a78f-557d3fcc53c9' User entered '0'	System	07 Jan 2021 13:16:43

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-01-07T08:16:10', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'fd7ddf47-99fa-4337-a78f-557d3fcc53c9' User entered '0'	System	07 Jan 2021 13:16:43

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-01-07T08:16:10', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'fd7ddf47-99fa-4337-a78f-557d3fcc53c9' User entered '0'	System	07 Jan 2021 13:16:43

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-01-07T08:16:10', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'fd7ddf47-99fa-4337-a78f-557d3fcc53c9' User entered '0'	System	07 Jan 2021 13:16:43

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-01-07T08:16:10', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'fd7ddf47-99fa-4337-a78f-557d3fcc53c9' User entered '0'	System	07 Jan 2021 13:16:43

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-01-07T08:16:10', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'fd7ddf47-99fa-4337-a78f-557d3fcc53c9'	System	07 Jan 2021 13:16:43
User entered '0'	System	07 Jan 2021 13:16:43

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-01-07T08:16:10', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'fd7ddf47-99fa-4337-a78f-557d3fcc53c9' User entered '0'	System	07 Jan 2021 13:16:43
	System	07 Jan 2021 13:16:43

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-01-07T08:16:10', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'fd7ddf47-99fa-4337-a78f-557d3fcc53c9' User entered '0'	System	07 Jan 2021 13:16:43

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Please 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 (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-01-07T08:16:18', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'fd7ddf47-99fa-4337-a78f-557d3fcc53c9'	System	07 Jan 2021 13:16:43
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	07 Jan 2021 13:16:43

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[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 (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-01-07T08:16:30', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'fd7ddf47-99fa-4337-a78f-557d3fcc53c9' User entered 'No (N)'	System	07 Jan 2021 13:16:43

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-01-07T08:16:33', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'fd7ddf47-99fa-4337-a78f-557d3fcc53c9' User entered '07 Jan 2021 08:16:33'	System	07 Jan 2021 13:16:43

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '07 Jan 2021 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '11 Jan 2021 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[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 (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-01-16T12:26:10', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '1281e74f-8942-4228-819b-cf94f4c3c621'	System	16 Jan 2021 17:26:23
User entered 'No (N)'	System	16 Jan 2021 17:26:23

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

Have you been exposed to someone with 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 (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-01-16T12:26:16', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '1281e74f-8942-4228-819b-cf94f4c3c621'	System	16 Jan 2021 17:26:23
User entered 'No (N)'	System	16 Jan 2021 17:26:23

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-01-16T12:26:19', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '1281e74f-8942-4228-819b-cf94f4c3c621' User entered '16 Jan 2021 12:26:19'	System	16 Jan 2021 17:26:23
	System	16 Jan 2021 17:26:23

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '14 Jan 2021 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '18 Jan 2021 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[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 (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-01-23T12:10:26', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '7817d33d-59ab-4f13-958f-edf1ede0777b'	System	23 Jan 2021 17:10:36
User entered 'No (N)'	System	23 Jan 2021 17:10:36

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

Have you been exposed to someone with 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 (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-01-23T12:10:28', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '7817d33d-59ab-4f13-958f-edf1ede0777b'	System	23 Jan 2021 17:10:36
User entered 'No (N)'	System	23 Jan 2021 17:10:36

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-01-23T12:10:31', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '7817d33d-59ab-4f13-958f-edf1ede0777b' User entered '23 Jan 2021 12:10:31'	System	23 Jan 2021 17:10:36
	System	23 Jan 2021 17:10:36

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '21 Jan 2021 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '25 Jan 2021 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[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 (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-01-30T13:45:02', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '51485712-871b-48de-8c4e-ad5fadd5a83c' User entered 'No (N)'	System	30 Jan 2021 18:45:10
	System	30 Jan 2021 18:45:10

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

Have you been exposed to someone with 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 (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-01-30T13:45:05', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '51485712-871b-48de-8c4e-ad5fadd5a83c'	System	30 Jan 2021 18:45:10
User entered 'No (N)'	System	30 Jan 2021 18:45:10

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-01-30T13:45:08', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '51485712-871b-48de-8c4e-ad5fadd5a83c' User entered '30 Jan 2021 13:45:08'	System	30 Jan 2021 18:45:10
	System	30 Jan 2021 18:45:10

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '28 Jan 2021 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '01 Feb 2021 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[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 (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-02-06T12:07:39', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '5179efea-45f0-4948-ba26-c6357da1a4c1' User entered 'No (N)'	System	06 Feb 2021 17:10:26
	System	06 Feb 2021 17:10:26

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

Have you been exposed to someone with 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 (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-02-06T12:07:42', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '5179efea-45f0-4948-ba26-c6357da1a4c1' User entered 'No (N)'	System	06 Feb 2021 17:10:26
	System	06 Feb 2021 17:10:26

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-02-06T12:07:45', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '5179efea-45f0-4948-ba26-c6357da1a4c1' User entered '06 Feb 2021 12:07:45'	System	06 Feb 2021 17:10:26
	System	06 Feb 2021 17:10:26

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '04 Feb 2021 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '08 Feb 2021 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[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 (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-02-11T12:39:59', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '767f1863-ee3b-4842-868f-d22a1d2ab5ac'	System	11 Feb 2021 17:40:22
User entered 'Yes (Y)'	System	11 Feb 2021 17:40:22

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

Have you been exposed to someone with 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 (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-02-11T12:40:03', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '767f1863-ee3b-4842-868f-d22a1d2ab5ac'	System	11 Feb 2021 17:40:22
User entered 'No (N)'	System	11 Feb 2021 17:40:22

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[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 (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-02-11T12:40:11', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '767f1863-ee3b-4842-868f-d22a1d2ab5ac'	System	11 Feb 2021 17:40:22
User entered 'No (N)'	System	11 Feb 2021 17:40:22

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[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 (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-02-11T12:40:16', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '767f1863-ee3b-4842-868f-d22a1d2ab5ac' User entered 'No (N)'	System	11 Feb 2021 17:40:22

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-02-11T12:40:20', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '767f1863-ee3b-4842-868f-d22a1d2ab5ac'	System	11 Feb 2021 17:40:22
User entered '11 Feb 2021 12:40:20'	System	11 Feb 2021 17:40:22

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '11 Feb 2021 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '15 Feb 2021 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '18 Feb 2021 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '22 Feb 2021 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[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 (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-02-27T12:00:31-05:00', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '61da8e8f-470a-48c2-9d21-5d94ae7ad030'	System	27 Feb 2021 17:00:55
User entered 'No (N)'	System	27 Feb 2021 17:00:55

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

Have you been exposed to someone with 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 (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-02-27T12:00:35-05:00', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '61da8e8f-470a-48c2-9d21-5d94ae7ad030'	System	27 Feb 2021 17:00:55
User entered 'No (N)'	System	27 Feb 2021 17:00:55

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-02-27T12:00:38-05:00', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '61da8e8f-470a-48c2-9d21-5d94ae7ad030'	System	27 Feb 2021 17:00:55
User entered '27 Feb 2021 17:00:38'	System	27 Feb 2021 17:00:55

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '25 Feb 2021 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '01 Mar 2021 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

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 (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-03-04T06:55:54-05:00', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '5172dc75-7d62-4e3c-9d52-4efd75e52ede' User entered 'No (N)'	System	04 Mar 2021 11:56:28
	System	04 Mar 2021 11:56:28

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

Have you been exposed to someone with 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 (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-03-04T06:55:58-05:00', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '5172dc75-7d62-4e3c-9d52-4efd75e52ede' User entered 'No (N)'	System	04 Mar 2021 11:56:28

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-03-04T06:56:01-05:00', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '5172dc75-7d62-4e3c-9d52-4efd75e52ede' User entered '04 Mar 2021 06:56:01'	System	04 Mar 2021 11:56:28
	System	04 Mar 2021 11:56:28

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '04 Mar 2021 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '08 Mar 2021 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[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 (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-03-11T12:10:38-05:00', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '43783b32-e0f5-46a6-9d6f-83d57b0bf87a' User entered 'No (N)'	System	11 Mar 2021 17:14:29
	System	11 Mar 2021 17:14:29

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

Have you been exposed to someone with 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 (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-03-11T12:10:40-05:00', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '43783b32-e0f5-46a6-9d6f-83d57b0bf87a'	System	11 Mar 2021 17:14:29
User entered 'No (N)'	System	11 Mar 2021 17:14:29

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-03-11T12:10:43-05:00', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '43783b32-e0f5-46a6-9d6f-83d57b0bf87a' User entered '11 Mar 2021 12:10:43'	System	11 Mar 2021 17:14:29
	System	11 Mar 2021 17:14:29

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '11 Mar 2021 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '15 Mar 2021 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[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 (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-03-18T09:51:29-04:00', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '860fb451-236f-46ee-9533-dc1f9d264933'	System	18 Mar 2021 13:51:39
User entered 'No (N)'	System	18 Mar 2021 13:51:39

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

Have you been exposed to someone with 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 (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-03-18T09:51:31-04:00', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '860fb451-236f-46ee-9533-dc1f9d264933'	System	18 Mar 2021 13:51:39
User entered 'No (N)'	System	18 Mar 2021 13:51:39

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-03-18T09:51:34-04:00', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '860fb451-236f-46ee-9533-dc1f9d264933'	System	18 Mar 2021 13:51:39
User entered '18 Mar 2021 09:51:34'	System	18 Mar 2021 13:51:39

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '18 Mar 2021 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '22 Mar 2021 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[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 (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-03-25T00:06:47-04:00', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '2a05910e-1f26-42bb-a5f4-0767e3dc03'	System	25 Mar 2021 04:06:56
User entered 'No (N)'	System	25 Mar 2021 04:06:56

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

Have you been exposed to someone with 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 (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-03-25T00:06:49-04:00', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '2a05910e-1f26-42bb-a5f4-0767e3dc03'	System	25 Mar 2021 04:06:56
User entered 'No (N)'	System	25 Mar 2021 04:06:56

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-03-25T00:06:51-04:00', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '2a05910e-1f26-42bb-a5f4-0767e3dc03'	System	25 Mar 2021 04:06:56
User entered '25 Mar 2021 00:06:51'	System	25 Mar 2021 04:06:56

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '25 Mar 2021 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '29 Mar 2021 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[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 (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-04-04T17:59:23-04:00', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '897dfd45-f1e8-463b-8646-ee8fb8057ebb' User entered 'No (N)'	System	10 Apr 2021 16:58:16

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

Have you been exposed to someone with 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 (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-04-04T17:59:25-04:00', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '897dfd45-f1e8-463b-8646-ee8fb8057ebb'	System	10 Apr 2021 16:58:16
User entered 'No (N)'	System	10 Apr 2021 16:58:16

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-04-04T17:59:27-04:00', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '897dfd45-f1e8-463b-8646-ee8fb8057ebb' User entered '04 Apr 2021 17:59:27'	System	10 Apr 2021 16:58:16
	System	10 Apr 2021 16:58:16

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '01 Apr 2021 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '05 Apr 2021 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[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 (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-04-10T12:58:13-04:00', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'e8a30345-dfea-4c99-b8e3-b302b20034f3' User entered 'No (N)'	System	10 Apr 2021 16:58:19

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

Have you been exposed to someone with 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 (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-04-10T12:58:15-04:00', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'e8a30345-dfea-4c99-b8e3-b302b20034f3' User entered 'No (N)'	System	10 Apr 2021 16:58:19

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-04-10T12:58:17-04:00', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'e8a30345-dfea-4c99-b8e3-b302b20034f3'	System	10 Apr 2021 16:58:19
User entered '10 Apr 2021 12:58:17'	System	10 Apr 2021 16:58:19

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '08 Apr 2021 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '12 Apr 2021 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[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 (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-04-15T07:30:40-04:00', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '9541a0f4-a8f5-4754-a0c3-c9fe51ea602a' User entered 'No (N)'	System	15 Apr 2021 11:30:58

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

Have you been exposed to someone with 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 (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-04-15T07:30:42-04:00', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '9541a0f4-a8f5-4754-a0c3-c9fe51ea602a' User entered 'No (N)'	System	15 Apr 2021 11:30:58

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-04-15T07:30:55-04:00', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '9541a0f4-a8f5-4754-a0c3-c9fe51ea602a' User entered '15 Apr 2021 07:30:55'	System	15 Apr 2021 11:30:58
	System	15 Apr 2021 11:30:58

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '15 Apr 2021 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '19 Apr 2021 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[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 (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-04-22T00:08:17-04:00', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '2eaa84f0-d7b3-4728-8af7-561a7417b7bc'	System	22 Apr 2021 04:08:31
User entered 'No (N)'	System	22 Apr 2021 04:08:31

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

Have you been exposed to someone with 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 (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-04-22T00:08:20-04:00', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '2eaa84f0-d7b3-4728-8af7-561a7417b7bc'	System	22 Apr 2021 04:08:31
User entered 'No (N)'	System	22 Apr 2021 04:08:31

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-04-22T00:08:26-04:00', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '2eaa84f0-d7b3-4728-8af7-561a7417b7bc'	System	22 Apr 2021 04:08:31
User entered '22 Apr 2021 00:08:26'	System	22 Apr 2021 04:08:31

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '22 Apr 2021 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '26 Apr 2021 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[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 (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-04-29T00:02:15-04:00', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '0b0acb3a-a477-4d65-9d0f-38dcfd296549' User entered 'No (N)'	System	29 Apr 2021 04:03:29
	System	29 Apr 2021 04:03:29

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

Have you been exposed to someone with 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 (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-04-29T00:02:17-04:00', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '0b0acb3a-a477-4d65-9d0f-38dcfd296549' User entered 'No (N)'	System	29 Apr 2021 04:03:29

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-04-29T00:02:21-04:00', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: '0b0acb3a-a477-4d65-9d0f-38dcfd296549' User entered '29 Apr 2021 00:02:21'	System	29 Apr 2021 04:03:29
	System	29 Apr 2021 04:03:29

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '29 Apr 2021 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '03 May 2021 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '06 May 2021 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '10 May 2021 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '13 May 2021 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '17 May 2021 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '20 May 2021 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '24 May 2021 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '27 May 2021 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '31 May 2021 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '03 Jun 2021 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '07 Jun 2021 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '10 Jun 2021 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '14 Jun 2021 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '17 Jun 2021 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '21 Jun 2021 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '24 Jun 2021 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '28 Jun 2021 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '01 Jul 2021 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '05 Jul 2021 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '08 Jul 2021 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '12 Jul 2021 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '15 Jul 2021 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '19 Jul 2021 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '22 Jul 2021 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '26 Jul 2021 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '29 Jul 2021 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '02 Aug 2021 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '05 Aug 2021 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '09 Aug 2021 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '12 Aug 2021 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '16 Aug 2021 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '19 Aug 2021 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '23 Aug 2021 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '26 Aug 2021 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '30 Aug 2021 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '02 Sep 2021 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '06 Sep 2021 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '09 Sep 2021 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '13 Sep 2021 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '16 Sep 2021 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '20 Sep 2021 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '23 Sep 2021 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '27 Sep 2021 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '30 Sep 2021 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '04 Oct 2021 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '07 Oct 2021 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '11 Oct 2021 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '14 Oct 2021 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '18 Oct 2021 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '21 Oct 2021 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '25 Oct 2021 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '28 Oct 2021 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '01 Nov 2021 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '04 Nov 2021 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '08 Nov 2021 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '11 Nov 2021 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '15 Nov 2021 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '18 Nov 2021 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '22 Nov 2021 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '25 Nov 2021 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '29 Nov 2021 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '02 Dec 2021 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '06 Dec 2021 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '09 Dec 2021 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '13 Dec 2021 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '16 Dec 2021 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '20 Dec 2021 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '23 Dec 2021 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '27 Dec 2021 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '30 Dec 2021 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '03 Jan 2022 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '06 Jan 2022 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '10 Jan 2022 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '13 Jan 2022 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '17 Jan 2022 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '20 Jan 2022 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '24 Jan 2022 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '27 Jan 2022 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '31 Jan 2022 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '03 Feb 2022 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '07 Feb 2022 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '10 Feb 2022 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '14 Feb 2022 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '17 Feb 2022 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '21 Feb 2022 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '24 Feb 2022 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '28 Feb 2022 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '03 Mar 2022 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '07 Mar 2022 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '10 Mar 2022 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '14 Mar 2022 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '17 Mar 2022 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '21 Mar 2022 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '24 Mar 2022 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '28 Mar 2022 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '31 Mar 2022 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '04 Apr 2022 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '07 Apr 2022 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '11 Apr 2022 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '14 Apr 2022 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '18 Apr 2022 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '21 Apr 2022 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '25 Apr 2022 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '28 Apr 2022 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '02 May 2022 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '05 May 2022 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '09 May 2022 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '12 May 2022 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '16 May 2022 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '19 May 2022 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '23 May 2022 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '26 May 2022 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '30 May 2022 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '02 Jun 2022 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '06 Jun 2022 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '09 Jun 2022 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '13 Jun 2022 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '16 Jun 2022 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '20 Jun 2022 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '23 Jun 2022 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '27 Jun 2022 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '30 Jun 2022 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '04 Jul 2022 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '07 Jul 2022 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '11 Jul 2022 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '14 Jul 2022 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '18 Jul 2022 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '21 Jul 2022 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '25 Jul 2022 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '28 Jul 2022 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '01 Aug 2022 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '04 Aug 2022 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '08 Aug 2022 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '11 Aug 2022 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '15 Aug 2022 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '18 Aug 2022 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '22 Aug 2022 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 12:25:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '25 Aug 2022 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '29 Aug 2022 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '01 Sep 2022 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '05 Sep 2022 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '08 Sep 2022 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '12 Sep 2022 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '15 Sep 2022 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '19 Sep 2022 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '22 Sep 2022 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '26 Sep 2022 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '29 Sep 2022 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '03 Oct 2022 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '06 Oct 2022 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '10 Oct 2022 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '13 Oct 2022 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '17 Oct 2022 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '20 Oct 2022 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '24 Oct 2022 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '27 Oct 2022 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '31 Oct 2022 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '03 Nov 2022 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '07 Nov 2022 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '10 Nov 2022 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '14 Nov 2022 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '17 Nov 2022 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '21 Nov 2022 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '24 Nov 2022 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '28 Nov 2022 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '01 Dec 2022 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '05 Dec 2022 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '08 Dec 2022 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '12 Dec 2022 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '15 Dec 2022 00:01'	System	20 Nov 2020 12:25:15

US3482286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:25:15
Amendment Manager: User entered '19 Dec 2022 23:59'	System	20 Nov 2020 12:25:15

US3482286

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:51:52

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 13:06:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-02-27T12:00:42-05:00', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'ca365f5e-6c10-40cc-ad6d-41151f79401c'	System	27 Feb 2021 17:01:16
User entered 'No (N)'	System	27 Feb 2021 17:01:16

US3482286

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:51:52

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:06:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB536908-B9F2-4898-B095-1948FBE0BA30)', Time: '2021-02-27T12:00:46-05:00', User OID: 'PatientReportedOutcome (US3482286)', ODM File OID: 'ca365f5e-6c10-40cc-ad6d-41151f79401c' User entered '27 Feb 2021 17:00:46'	System	27 Feb 2021 17:01:16
	System	27 Feb 2021 17:01:16

US3482286

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:51:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:44:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Yes (Y)'	(b) (4) Amy Anderson (b) (4)	10 Jan 2021 15:15:48

US3482286

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:44:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '10 Jan 2021'	(b) (4) Amy Anderson (b) (4)	10 Jan 2021 15:15:48

US3482286

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:51:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:44:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Amy Anderson (b) (4)	10 Jan 2021 15:15:48

US3482286

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:51:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:44:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered empty.	(b) (4) Amy Anderson (b) (4)	10 Jan 2021 15:15:48
	(b) (4)	

US3482286

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:51:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:44:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Yes (Y)'	(b) (4) Amy Anderson (b) (4)	10 Jan 2021 15:15:53

US3482286

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:51:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:44:10
User entered 'I'	System	10 Jan 2021 15:15:53

US3482286

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:51:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:49:21
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	10 Feb 2021 15:56:09

US3482286

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:49:21
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '10 Feb 2021'	(b) (4) Sarah Bechnak (b) (4)	10 Feb 2021 15:56:09

US3482286

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:51:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:49:21
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	10 Feb 2021 15:56:09

US3482286

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:51:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:49:21
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	10 Feb 2021 15:56:09

US3482286

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:51:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:49:21
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	10 Feb 2021 15:56:16

US3482286

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:51:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:49:21
User entered 'I'	System	10 Feb 2021 15:56:16

US3482286

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:51:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:49:21
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	(b) (4) System	12 Mar 2021 13:53:47
User entered 'Yes (Y)' reason for change: Data Entry Error	Amy Anderson (b) (4) (b) (4)	12 Mar 2021 13:53:47
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	12 Mar 2021 13:53:40
User entered 'No (N)'	Amy Anderson (b) (4) (b) (4)	12 Mar 2021 13:53:40

US3482286

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:49:21
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '12 Mar 2021'	Amy Anderson (b) (4)	12 Mar 2021 13:53:40

US3482286

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:51:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:49:21
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Amy Anderson (b) (4)	12 Mar 2021 13:53:40

US3482286

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:51:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:49:21
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered empty.	(b) (4) Amy Anderson (b) (4)	12 Mar 2021 13:53:40

US3482286

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:51:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:49:21
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Yes (Y)'	(b) (4) Amy Anderson (b) (4)	12 Mar 2021 13:53:55

US3482286

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:51:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:49:21
User entered 'I'	System	12 Mar 2021 13:53:55

US3482286

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:51:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:20:28
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Apr 2021 17:24:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Apr 2021 17:24:03
User entered 'Yes (Y)' reason for change: Data Entry Error	Sarah Bechnak (b) (4)	08 Apr 2021 17:24:03
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Apr 2021 17:23:08
User entered empty; reason for change Data Entry Error	Sarah Bechnak (b) (4)	08 Apr 2021 17:23:08
	(b) (4)	
User entered 'Yes (Y)'	Sarah Bechnak (b) (4)	08 Apr 2021 17:19:34
	(b) (4)	

US3482286

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:51:52

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:11:40
Signature has been broken.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:14:12
User entered '14 Apr 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Apr 2021 17:14:12
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:20:28
User entered '8 Apr 2021' reason for change: Data Entry Error	Sarah Bechnak (b) (4)	08 Apr 2021 17:24:03
User entered empty; reason for change Data Entry Error	(b) (4) Sarah Bechnak (b) (4)	08 Apr 2021 17:23:08
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	08 Apr 2021 17:20:32
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	08 Apr 2021 17:20:32
User entered '8 Apr 2021' reason for change: Data Entry Error	Sarah Bechnak (b) (4)	08 Apr 2021 17:20:32
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) System	08 Apr 2021 17:19:34
User entered '7 Apr 2021'	Sarah Bechnak (b) (4)	08 Apr 2021 17:19:34

US3482286

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:51:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:20:28
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Sarah Bechnak (b) (4)	08 Apr 2021 17:24:03
reason for change: Data Entry Error	(b) (4)	
User entered empty; reason for change Data Entry Error	Sarah Bechnak (b) (4)	08 Apr 2021 17:23:08
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Sarah Bechnak (b) (4)	08 Apr 2021 17:19:34
	(b) (4)	

US3482286

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:51:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:20:28
	(b) (4)	
User entered empty.	Sarah Bechnak (b) (4)	08 Apr 2021 17:19:34
	(b) (4)	

US3482286

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:51:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:20:28
	(b) (4)	
User entered 'Yes (Y)'	Sarah Bechnak (b) (4)	08 Apr 2021 17:24:07
	(b) (4)	

US3482286

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:51:52

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Apr 2021 17:24:07

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:51:52

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:28
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:46:51
User entered '08 Jan 2021'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:11:49

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:51:52

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:28
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:46:51
User entered '08:10'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:11:49

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:51:52

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:28
User entered '08 Jan 2021 08:10'	System	08 Jan 2021 15:11:49

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:51:52

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:28
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:46:51
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:11:49

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID-19 Contact

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[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:28
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:46:51
User entered 'Yes (Y)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:11:49

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:51:52

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Day 1 (Day 1)'	(b) (4) Joy Winters (b) (4)	08 Jan 2021 15:13:31

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:51:52

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:52:03
User entered '04 Jan 2021'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:13:31

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:51:52

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:52:05
User entered '1'	Joy Winters (b) (4)	08 Jan 2021 15:13:31
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:51:52

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Feb 2021 16:07:34
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:52:06
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:13:31
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:51:52

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User entered '%'	System	08 Feb 2021 16:07:34
User entered empty.	System	08 Jan 2021 15:13:31

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:51:52

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Feb 2021 16:07:34
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:52:08
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:13:31
	(b) (4)	

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:51:52

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:52:09
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:13:31
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:51:52

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:51:59
User entered 'Mild (Mild)' reason for change: Data Entry Error	Joy Winters (b) (4)	08 Jan 2021 15:13:52
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:13:31

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:51:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:52:11
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:13:31
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:51:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 20:52:12
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:13:31
	(b) (4)	

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:51:52

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:51:51
User entered 'Mild (Mild)' reason for change: Data Entry Error	Joy Winters (b) (4)	08 Jan 2021 15:13:52
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:13:31

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:51:52

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 20:52:14
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:13:31
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:51:52

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:51:53
User entered 'Mild (Mild)' reason for change: Data Entry Error	Joy Winters (b) (4)	08 Jan 2021 15:13:52
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:13:31

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:51:52

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:51:55
User entered 'Mild (Mild)' reason for change: Data Entry Error	Joy Winters (b) (4)	08 Jan 2021 15:35:15
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:13:31

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:51:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:52:15
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:13:31
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:51:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:52:17
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:13:31
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:51:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:52:19
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:13:31
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:51:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:52:20
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:13:31
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:51:52

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:52:21
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:13:31
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:51:52

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:52:23
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:13:31
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:51:52

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:52:25
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:13:31
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:51:52

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:52:27
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:13:31
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:51:52

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Day 2 (Day 2)'	Joy Winters (b) (4)	08 Jan 2021 15:14:35

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:51:52

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:52:34
User entered '05 Jan 2021'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:14:35

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:51:52

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:52:36
User entered '1'	Joy Winters (b) (4)	08 Jan 2021 15:14:35
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:51:52

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Feb 2021 16:07:34
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:52:38
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:14:35
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:51:52

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User entered '%'	System	08 Feb 2021 16:07:34
User entered empty.	System	08 Jan 2021 15:14:35

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:51:52

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Feb 2021 16:07:34
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:52:40
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:14:35
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:51:52

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:52:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:14:35
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:51:52

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:52:42
User entered 'Mild (Mild)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:14:35

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:51:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:52:47
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:14:35
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:51:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:52:57
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:14:35
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:51:52

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:52:58
User entered 'Mild (Mild)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:14:35

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:51:52

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:52:59
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:14:35
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:51:52

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:53:01
User entered 'Mild (Mild)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:14:35

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:51:52

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:53:04
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:14:35
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:51:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:53:03
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:14:35
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:51:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:53:09
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:14:35
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:51:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:53:11
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:14:35
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:51:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:57:57
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:14:35
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:51:52

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:57:56
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:14:35
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:51:52

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:57:59
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:14:35
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:51:52

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:58:00
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:14:35
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:51:52

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:58:02
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:14:35
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:51:52

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Day 3 (Day 3)'	(b) (4) Joy Winters (b) (4)	08 Jan 2021 15:15:17

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:51:52

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:58:21
User entered '06 Jan 2021'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:15:17

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:51:52

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:58:23
User entered '1'	Joy Winters (b) (4)	08 Jan 2021 15:15:17
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:51:52

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Feb 2021 16:07:34
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:58:24
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:15:17
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:51:52

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User entered '%'	System	08 Feb 2021 16:07:34
User entered empty.	System	08 Jan 2021 15:15:17

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:51:52

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Feb 2021 16:07:34
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:58:26
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:15:17
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:51:52

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:58:27
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:15:17
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:51:52

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:59:16
User entered 'Mild (Mild)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:15:17

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:51:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:59:17
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:15:17
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:51:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:59:18
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:15:17
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:51:52

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:59:36
User entered 'Mild (Mild)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:15:17

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:51:52

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:59:37
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:15:17
	(b) (4)	

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Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:51:52

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:59:39
User entered 'Mild (Mild)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:15:17

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:51:52

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:59:40
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:15:17
	(b) (4)	

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Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:51:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:59:42
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:15:17
	(b) (4)	

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Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:51:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:59:43
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:15:17
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:51:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:59:45
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:15:17
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:51:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:59:48
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:15:17
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:51:52

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:59:49
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:15:17
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:51:52

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:59:51
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:15:17
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:51:52

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:59:52
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:15:17
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:51:52

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:59:54
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:15:17
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:51:52

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Day 4 (Day 4)'	Joy Winters (b) (4)	08 Jan 2021 15:15:52

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:51:52

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:00:37
User entered '07 Jan 2021'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:15:52

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:51:52

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:00:34
User entered '1'	Joy Winters (b) (4)	08 Jan 2021 15:15:52
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:51:52

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Feb 2021 16:07:34
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:00:33
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:15:52
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:51:52

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User entered '%'	System	08 Feb 2021 16:07:34
User entered empty.	System	08 Jan 2021 15:15:52

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:51:52

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Feb 2021 16:07:34
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:00:31
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:15:52
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:51:52

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:00:30
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:15:52
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:51:52

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:00:28
User entered 'Mild (Mild)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:15:52

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:51:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:00:26
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:15:52
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:51:52

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:00:25
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:15:52
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:51:52

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:00:23
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:15:52
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:51:52

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:00:21
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:15:52
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:51:52

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:00:20
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:15:52
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:51:52

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:00:18
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:15:52
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:51:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:00:17
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:15:52
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:51:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:00:16
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:15:52
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:51:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:00:14
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:15:52
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:51:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:00:12
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:15:52
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:51:52

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:00:10
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:15:52
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:51:52

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:00:09
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:15:52
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:51:52

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:00:07
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:15:52
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:51:52

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	08 Feb 2021 16:07:34
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:00:06
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:15:52
	(b) (4)	

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Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:51:52

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Day 5 (Day 5)'	Joy Winters (b) (4)	08 Jan 2021 15:17:39

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:51:52

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:00:51
User entered '08 Jan 2021'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:17:39

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:51:52

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:00:53
User entered '0'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:17:39

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:51:52

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:00:56
User entered '93'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:17:39

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:51:52

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User entered '%'	System	08 Jan 2021 15:17:39

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:51:52

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:00:57
User entered '98.9' F	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:17:39

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:51:52

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:01:16
User entered 'None (None)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:17:39

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:51:52

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:01:18
User entered 'Mild (Mild)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:17:39

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:51:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:01:20
User entered 'None (None)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:17:39

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:51:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:01:26
User entered 'None (None)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:17:39

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:51:52

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:01:27
User entered 'None (None)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:17:39

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:51:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:01:29
User entered 'None (None)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:17:39

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:51:52

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:01:30
User entered 'None (None)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:17:39

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:51:52

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:01:31
User entered 'None (None)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:17:39

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:51:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:01:33
User entered 'None (None)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:17:39

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:51:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:01:34
User entered 'None (None)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:17:39

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:51:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:01:36
User entered 'None (None)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:17:39

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:51:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:01:38
User entered 'None (None)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:17:39

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:51:52

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:01:40
User entered 'None (None)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:17:39

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:51:52

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:01:42
User entered 'None (None)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:17:39

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:51:52

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:01:44
User entered 'None (None)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:17:39

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:51:52

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:01:45
User entered 'None (None)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:17:39

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:51:52

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Day 6 (Day 6)'	(b) (4) Amy Anderson (b) (4)	10 Jan 2021 15:06:39

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:51:52

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:07:17
User entered '09 Jan 2021'	Amy Anderson (b) (4) (b) (4)	10 Jan 2021 15:06:39

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:51:52

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:07:19
User entered '0'	Amy Anderson (b) (4) (b) (4)	10 Jan 2021 15:06:39

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:51:52

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:07:23
User entered missing code ND - Not Done.	Amy Anderson (b) (4) (b) (4)	10 Jan 2021 15:06:39

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:51:52

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User entered '%'	System	10 Jan 2021 15:06:39

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:51:52

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:07:24
User entered missing code ND - Not Done.	Amy Anderson (b) (4) (b) (4)	10 Jan 2021 15:06:39

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:51:52

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:07:26
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	10 Jan 2021 15:06:39

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:51:52

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:07:27
User entered 'Mild (Mild)'	Amy Anderson (b) (4) (b) (4)	10 Jan 2021 15:06:39

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:51:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:07:29
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	10 Jan 2021 15:06:39

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:51:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:07:30
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	10 Jan 2021 15:06:39

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:51:52

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:07:32
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	10 Jan 2021 15:06:39

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:51:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:07:34
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	10 Jan 2021 15:06:39

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:51:52

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:07:35
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	10 Jan 2021 15:06:39

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:51:52

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:07:37
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	10 Jan 2021 15:06:39

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:51:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:07:44
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	10 Jan 2021 15:06:39

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:51:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:07:46
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	10 Jan 2021 15:06:39

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:51:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:07:47
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	10 Jan 2021 15:06:39

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:51:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:07:49
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	10 Jan 2021 15:06:39

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:51:52

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:07:50
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	10 Jan 2021 15:06:39

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:51:52

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:07:52
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	10 Jan 2021 15:06:39

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:51:52

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:07:53
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	10 Jan 2021 15:06:39

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:51:52

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:07:55
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	10 Jan 2021 15:06:39

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:51:52

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Day 7 (Day 7)'	(b) (4) Amy Anderson (b) (4)	10 Jan 2021 15:07:52

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:51:52

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:20:28
User entered '10 Jan 2021'	Amy Anderson (b) (4) (b) (4)	10 Jan 2021 15:07:52

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:51:52

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:20:29
User entered '0'	Amy Anderson (b) (4) (b) (4)	10 Jan 2021 15:07:52

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:51:52

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:20:24
User entered '96'	Amy Anderson (b) (4) (b) (4)	10 Jan 2021 15:07:52

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:51:52

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User entered '%'	System	10 Jan 2021 15:07:52

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:51:52

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:20:25
User entered '98.1' F	Amy Anderson (b) (4) (b) (4)	10 Jan 2021 15:07:52

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:51:52

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:20:31
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	10 Jan 2021 15:07:52

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:51:52

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:20:34
User entered 'Mild (Mild)'	Amy Anderson (b) (4) (b) (4)	10 Jan 2021 15:07:52

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:51:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:20:38
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	10 Jan 2021 15:07:52

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:51:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:22:34
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	10 Jan 2021 15:07:52

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:51:52

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:22:36
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	10 Jan 2021 15:07:52

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:51:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:20:42
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	10 Jan 2021 15:07:52

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:51:52

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:20:40
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amy Anderson (b) (4)	11 Jan 2021 15:47:02
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4)	10 Jan 2021 15:07:52

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:51:52

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:22:39
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	10 Jan 2021 15:07:52

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:51:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:22:43
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	10 Jan 2021 15:07:52

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:51:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:22:44
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	10 Jan 2021 15:07:52

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:51:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:22:45
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	10 Jan 2021 15:07:52

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:51:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:22:47
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	10 Jan 2021 15:07:52

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:51:52

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:22:49
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	10 Jan 2021 15:07:52

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:51:52

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:22:50
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	10 Jan 2021 15:07:52

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:51:52

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:22:52
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	10 Jan 2021 15:07:52

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:51:52

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:22:55
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	10 Jan 2021 15:07:52

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:51:52

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Day 8 (Day 8)'	(b) (4) Amy Anderson (b) (4)	11 Jan 2021 15:47:02

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:51:52

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:23:44
User entered '11 Jan 2021'	Amy Anderson (b) (4) (b) (4)	11 Jan 2021 15:47:02

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:51:52

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:23:46
User entered '0'	Amy Anderson (b) (4) (b) (4)	11 Jan 2021 15:47:02

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:51:52

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:23:48
User entered '96'	Amy Anderson (b) (4) (b) (4)	11 Jan 2021 15:47:02

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:51:52

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User entered '%'	System	11 Jan 2021 15:47:02

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:51:52

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:23:49
User entered '98.5' F	Amy Anderson (b) (4) (b) (4)	11 Jan 2021 15:47:02

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:51:52

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:23:51
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	11 Jan 2021 15:47:02

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:51:52

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:23:52
User entered 'Mild (Mild)'	Amy Anderson (b) (4) (b) (4)	11 Jan 2021 15:47:02

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:51:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:23:54
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	11 Jan 2021 15:47:02

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:51:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:23:57
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	11 Jan 2021 15:47:02

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:51:52

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:24:02
User entered 'Mild (Mild)'	Amy Anderson (b) (4) (b) (4)	11 Jan 2021 15:47:02

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:51:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:24:04
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	11 Jan 2021 15:47:02

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:51:52

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:24:06
User entered 'Mild (Mild)'	Amy Anderson (b) (4) (b) (4)	11 Jan 2021 15:47:02

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:51:52

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:24:07
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	11 Jan 2021 15:47:02

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:51:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:24:09
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	11 Jan 2021 15:47:02

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:51:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:24:10
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	11 Jan 2021 15:47:02

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:51:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:24:12
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	11 Jan 2021 15:47:02

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:51:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:24:13
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	11 Jan 2021 15:47:02

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:51:52

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:24:15
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	11 Jan 2021 15:47:02

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:51:52

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:24:16
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	11 Jan 2021 15:47:02

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:51:52

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:24:18
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	11 Jan 2021 15:47:02

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:51:52

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:24:19
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	11 Jan 2021 15:47:02

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:51:52

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Day 9 (Day 9)'	(b) (4) Amy Anderson (b) (4)	12 Jan 2021 13:41:06

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:51:52

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:39:50
User entered '12 Jan 2021'	Amy Anderson (b) (4) (b) (4)	12 Jan 2021 13:41:06

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:51:52

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:39:51
User entered '0'	Amy Anderson (b) (4) (b) (4)	12 Jan 2021 13:41:06

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:51:52

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:39:53
User entered '95' reason for change: Data Entry Error	Amy Anderson (b) (4)	13 Jan 2021 14:38:23
User entered '97'	(b) (4) Amy Anderson (b) (4) (b) (4)	12 Jan 2021 13:41:06

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:51:52

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User entered '%'	System	12 Jan 2021 13:41:06

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:51:52

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:39:55
User entered '101.5' F reason for change: Data Entry Error	Amy Anderson (b) (4) (b) (4)	13 Jan 2021 14:38:23
User entered '98.8' F	Amy Anderson (b) (4) (b) (4)	12 Jan 2021 13:41:06

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:51:52

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:39:58
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Amy Anderson (b) (4) (b) (4)	13 Jan 2021 14:38:23
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	12 Jan 2021 13:41:06

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:51:52

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:40:00
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amy Anderson (b) (4)	13 Jan 2021 14:38:23
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	12 Jan 2021 13:41:06

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:51:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:40:02
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	12 Jan 2021 13:41:06

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:51:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:40:04
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	12 Jan 2021 13:41:06

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:51:52

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:40:05
User entered 'Severe (Severe)' reason for change: Data Entry Error	Amy Anderson (b) (4) (b) (4)	13 Jan 2021 14:38:23
User entered 'Mild (Mild)'	Amy Anderson (b) (4) (b) (4)	12 Jan 2021 13:41:06

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:51:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:40:07
User entered 'Severe (Severe)' reason for change: Data Entry Error	Amy Anderson (b) (4) (b) (4)	13 Jan 2021 14:38:23
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	12 Jan 2021 13:41:06

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:51:52

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:40:08
User entered 'Severe (Severe)' reason for change: Data Entry Error	Amy Anderson (b) (4) (b) (4)	13 Jan 2021 14:38:23
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	12 Jan 2021 13:41:06

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:51:52

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:40:11
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	12 Jan 2021 13:41:06

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:51:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:40:27
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	12 Jan 2021 13:41:06

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:51:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:40:29
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	12 Jan 2021 13:41:06

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:51:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:40:30
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	12 Jan 2021 13:41:06

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:51:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:40:32
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	12 Jan 2021 13:41:06

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:51:52

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:40:33
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	12 Jan 2021 13:41:06

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:51:52

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:40:35
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	12 Jan 2021 13:41:06

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:51:52

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:40:36
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	12 Jan 2021 13:41:06

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:51:52

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:40:38
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	12 Jan 2021 13:41:06

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:51:52

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Day 10 (Day 10)'	(b) (4) Amy Anderson (b) (4)	13 Jan 2021 14:47:38

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:51:52

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:40:56
User entered '13 Jan 2021'	Amy Anderson (b) (4) (b) (4)	13 Jan 2021 14:47:38

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:51:52

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:40:57
User entered '0'	Amy Anderson (b) (4) (b) (4)	13 Jan 2021 14:47:38

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:51:52

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:40:59
User entered '95'	Amy Anderson (b) (4) (b) (4)	13 Jan 2021 14:47:38

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:51:52

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User entered '%'	System	13 Jan 2021 14:47:38

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:51:52

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:41:01
User entered '100.1' F	Amy Anderson (b) (4) (b) (4)	13 Jan 2021 14:47:38

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:51:52

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:41:08
DataPoint Un-verified.	(b) (4), (b) (6)	20 Jan 2021 21:41:04
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:41:03
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	13 Jan 2021 14:47:38

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:51:52

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:41:06
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	13 Jan 2021 14:47:38

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:51:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:41:10
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	13 Jan 2021 14:47:38

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:51:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:41:12
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	13 Jan 2021 14:47:38

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:51:52

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:41:32
User entered 'Moderate (Moderate)'	Amy Anderson (b) (4) (b) (4)	13 Jan 2021 14:47:38

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:51:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:41:34
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	13 Jan 2021 14:47:38

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:51:52

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:41:46
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	13 Jan 2021 14:47:38

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:51:52

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:41:48
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	13 Jan 2021 14:47:38

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:51:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:41:50
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	13 Jan 2021 14:47:38

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:51:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:41:51
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	13 Jan 2021 14:47:38

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:51:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:41:53
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	13 Jan 2021 14:47:38

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:51:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:41:55
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	13 Jan 2021 14:47:38

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:51:52

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:41:57
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	13 Jan 2021 14:47:38

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:51:52

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:41:58
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	13 Jan 2021 14:47:38

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:51:52

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:42:01
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	13 Jan 2021 14:47:38

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:51:52

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:42:03
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	13 Jan 2021 14:47:38

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:51:52

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Day 11 (Day 11)' reason for change:	(b) (4)	
Data Entry Error	Amy Anderson (b) (4)	18 Jan 2021 15:49:30
User entered 'Day 14 (Day 14)'	(b) (4)	
	Amy Anderson (b) (4)	14 Jan 2021 14:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:51:52

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:42:35
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Jan 2021 14:23:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Jan 2021 14:23:12
User entered '14 Jan 2021' reason for change: Data Entry Error	Amy Anderson (b) (4) (b) (4)	14 Jan 2021 14:23:12
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Jan 2021 14:21:58
User entered empty.	Amy Anderson (b) (4) (b) (4)	14 Jan 2021 14:21:58

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Form: Symptom Log (11)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:42:34
User entered '0'	Amy Anderson (b) (4) (b) (4)	14 Jan 2021 14:21:58

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:51:52

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:42:37
User entered '98' reason for change: Data Entry Error	Amy Anderson (b) (4)	14 Jan 2021 14:23:12
User entered empty.	(b) (4) Amy Anderson (b) (4) (b) (4)	14 Jan 2021 14:21:58

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:51:52

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User entered '%'	System	14 Jan 2021 14:23:12
User entered empty.	System	14 Jan 2021 14:21:58

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:51:52

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:42:38
User entered '98' F reason for change: Data Entry Error	Amy Anderson (b) (4)	14 Jan 2021 14:23:12
User entered empty.	(b) (4) Amy Anderson (b) (4) (b) (4)	14 Jan 2021 14:21:58

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:51:52

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:42:40
User entered 'None (None)' reason for change: Data Entry Error	Amy Anderson (b) (4)	14 Jan 2021 14:23:12
User entered empty.	(b) (4) Amy Anderson (b) (4) (b) (4)	14 Jan 2021 14:21:58

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:51:52

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:42:42
User entered 'None (None)' reason for change: Data Entry Error	Amy Anderson (b) (4)	14 Jan 2021 14:23:12
User entered empty.	(b) (4) Amy Anderson (b) (4) (b) (4)	14 Jan 2021 14:21:58

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:51:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:42:48
User entered 'None (None)' reason for change: Data Entry Error	Amy Anderson (b) (4)	14 Jan 2021 14:23:12
User entered empty.	(b) (4) Amy Anderson (b) (4) (b) (4)	14 Jan 2021 14:21:58

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:51:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:42:49
User entered 'None (None)' reason for change: Data Entry Error	Amy Anderson (b) (4)	14 Jan 2021 14:23:12
User entered empty.	(b) (4) Amy Anderson (b) (4) (b) (4)	14 Jan 2021 14:21:58

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:51:52

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:42:51
User entered 'None (None)' reason for change: Data Entry Error	Amy Anderson (b) (4)	14 Jan 2021 14:23:12
User entered empty.	(b) (4) Amy Anderson (b) (4) (b) (4)	14 Jan 2021 14:21:58

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:51:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:42:53
User entered 'None (None)' reason for change: Data Entry Error	Amy Anderson (b) (4)	14 Jan 2021 14:23:12
User entered empty.	(b) (4) Amy Anderson (b) (4) (b) (4)	14 Jan 2021 14:21:58

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:51:52

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:42:54
User entered 'None (None)' reason for change: Data Entry Error	Amy Anderson (b) (4)	14 Jan 2021 14:23:12
User entered empty.	(b) (4) Amy Anderson (b) (4) (b) (4)	14 Jan 2021 14:21:58

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:51:52

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:42:56
User entered 'None (None)' reason for change: Data Entry Error	Amy Anderson (b) (4)	14 Jan 2021 14:23:12
User entered empty.	(b) (4) Amy Anderson (b) (4) (b) (4)	14 Jan 2021 14:21:58

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:51:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:42:57
User entered 'None (None)' reason for change: Data Entry Error	Amy Anderson (b) (4)	14 Jan 2021 14:23:12
User entered empty.	(b) (4) Amy Anderson (b) (4) (b) (4)	14 Jan 2021 14:21:58

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:51:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:42:59
User entered 'None (None)' reason for change: Data Entry Error	Amy Anderson (b) (4)	14 Jan 2021 14:23:12
User entered empty.	(b) (4) Amy Anderson (b) (4) (b) (4)	14 Jan 2021 14:21:58

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:51:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:43:05
User entered 'None (None)' reason for change: Data Entry Error	Amy Anderson (b) (4)	14 Jan 2021 14:23:12
User entered empty.	(b) (4) Amy Anderson (b) (4) (b) (4)	14 Jan 2021 14:21:58

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:51:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:43:07
User entered 'None (None)' reason for change: Data Entry Error	Amy Anderson (b) (4)	14 Jan 2021 14:23:12
User entered empty.	(b) (4) Amy Anderson (b) (4) (b) (4)	14 Jan 2021 14:21:58

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:51:52

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:43:08
User entered 'None (None)' reason for change: Data Entry Error	Amy Anderson (b) (4)	14 Jan 2021 14:23:12
User entered empty.	(b) (4) Amy Anderson (b) (4) (b) (4)	14 Jan 2021 14:21:58

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:51:52

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:43:10
User entered 'None (None)' reason for change: Data Entry Error	Amy Anderson (b) (4)	14 Jan 2021 14:23:12
User entered empty.	(b) (4) Amy Anderson (b) (4) (b) (4)	14 Jan 2021 14:21:58

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:51:52

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:43:11
User entered 'None (None)' reason for change: Data Entry Error	Amy Anderson (b) (4)	14 Jan 2021 14:23:12
User entered empty.	(b) (4) Amy Anderson (b) (4) (b) (4)	14 Jan 2021 14:21:58

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:51:52

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:43:13
User entered 'None (None)' reason for change: Data Entry Error	Amy Anderson (b) (4)	14 Jan 2021 14:23:12
User entered empty.	(b) (4) Amy Anderson (b) (4) (b) (4)	14 Jan 2021 14:21:58

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:51:52

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Day 12 (Day 12)' reason for change:	(b) (4)	
Data Entry Error	Amy Anderson (b) (4)	18 Jan 2021 15:49:30
User entered 'Day 15 (Day 15)'	(b) (4)	
	Amy Anderson (b) (4)	15 Jan 2021 13:54:52
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:51:52

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:44:06
User entered '15 Jan 2021'	Amy Anderson (b) (4) (b) (4)	15 Jan 2021 13:54:52

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:51:52

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:44:09
User entered '0'	Amy Anderson (b) (4) (b) (4)	15 Jan 2021 13:54:52

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:51:52

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:44:10
User entered '98'	Amy Anderson (b) (4) (b) (4)	15 Jan 2021 13:54:52

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:51:52

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User entered '%'	System	15 Jan 2021 13:54:52

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:51:52

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:44:12
User entered '98.6' F	Amy Anderson (b) (4) (b) (4)	15 Jan 2021 13:54:52

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:51:52

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:44:14
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	15 Jan 2021 13:54:52

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:51:52

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:44:19
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	15 Jan 2021 13:54:52

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:51:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:44:20
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	15 Jan 2021 13:54:52

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:51:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:44:30
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	15 Jan 2021 13:54:52

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:51:52

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:44:32
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	15 Jan 2021 13:54:52

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:51:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:44:38
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	15 Jan 2021 13:54:52

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:51:52

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:44:40
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	15 Jan 2021 13:54:52

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:51:52

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:44:41
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	15 Jan 2021 13:54:52

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:51:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:44:43
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	15 Jan 2021 13:54:52

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:51:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:44:44
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	15 Jan 2021 13:54:52

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:51:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:44:46
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	15 Jan 2021 13:54:52

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:51:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:44:47
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	15 Jan 2021 13:54:52

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:51:52

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:44:50
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	15 Jan 2021 13:54:52

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:51:52

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:44:51
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	15 Jan 2021 13:54:52

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:51:52

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:44:52
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	15 Jan 2021 13:54:52

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:51:52

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:44:54
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	15 Jan 2021 13:54:52

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:51:52

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Day 13 (Day 13)' reason for change:	(b) (4)	
Data Entry Error	Amy Anderson (b) (4)	18 Jan 2021 15:49:30
User entered 'Day 16 (Day 16)'	(b) (4)	
	Lauren Hewitt (b) (4)	17 Jan 2021 22:39:48
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:51:52

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:50:56
User entered '16 Jan 2021'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:39:48

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:51:52

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:50:59
User entered '0'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:39:48

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:51:52

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:51:00
User entered '99'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:39:48

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:51:52

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User entered '%'	System	17 Jan 2021 22:39:48

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:51:52

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:51:02
User entered '98.5' F	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:39:48

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:51:52

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:51:04
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:39:48

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:51:52

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:51:05
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:39:48

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:51:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:51:07
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:39:48

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:51:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:51:08
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:39:48

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:51:52

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:51:10
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:39:48

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:51:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:51:11
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:39:48

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:51:52

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:51:27
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:39:48

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:51:52

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:51:33
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:39:48

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:51:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:51:35
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:39:48

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:51:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:51:36
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:39:48

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:51:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:51:38
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:39:48

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:51:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:51:39
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:39:48

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:51:52

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:51:40
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:39:48

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:51:52

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:51:42
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:39:48

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:51:52

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:51:43
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:39:48

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:51:52

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:51:44
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:39:48

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:51:52

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Day 14 (Day 14)' reason for change:	(b) (4)	
Data Entry Error	Amy Anderson (b) (4)	18 Jan 2021 15:49:30
User entered 'Day 17 (Day 17)'	(b) (4)	
	Amy Anderson (b) (4)	18 Jan 2021 15:47:07
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:51:52

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User closed query 'Please complete form as per source.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:47:37
Query 'Please complete form as per source.' answered with 'done' (Site from CRA).	Amy Anderson (b) (4)	21 Jan 2021 17:55:37
User opened query 'Please complete form as per source.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:52:42
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:52:06
User entered '17 Jan 2021'	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:47:07

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:51:52

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:52:09
User entered '0'	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:47:07

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:51:52

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '98' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	21 Jan 2021 17:55:29
User entered empty.	(b) (4)	
	Amy Anderson (b) (4)	18 Jan 2021 15:47:07
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:51:52

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User entered '%'	System	21 Jan 2021 17:55:29
User entered empty.	System	18 Jan 2021 15:47:07

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:51:52

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '97.8' F reason for change: Data Entry Error	(b) (4)	
User entered empty.	Amy Anderson (b) (4)	21 Jan 2021 17:55:29
	(b) (4)	
	Amy Anderson (b) (4)	18 Jan 2021 15:47:07
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:51:52

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Amy Anderson (b) (4)	21 Jan 2021 17:55:29
	(b) (4)	
	Amy Anderson (b) (4)	18 Jan 2021 15:47:07
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:51:52

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Amy Anderson (b) (4)	21 Jan 2021 17:55:29
	(b) (4)	
	Amy Anderson (b) (4)	18 Jan 2021 15:47:07
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:51:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Amy Anderson (b) (4)	21 Jan 2021 17:55:29
	(b) (4)	
	Amy Anderson (b) (4)	18 Jan 2021 15:47:07
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:51:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Amy Anderson (b) (4)	21 Jan 2021 17:55:29
	(b) (4)	
	Amy Anderson (b) (4)	18 Jan 2021 15:47:07
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:51:52

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Amy Anderson (b) (4)	21 Jan 2021 17:55:29
	(b) (4)	
	Amy Anderson (b) (4)	18 Jan 2021 15:47:07
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:51:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Amy Anderson (b) (4)	21 Jan 2021 17:55:29
	(b) (4)	
	Amy Anderson (b) (4)	18 Jan 2021 15:47:07
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:51:52

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Amy Anderson (b) (4)	21 Jan 2021 17:55:29
	(b) (4)	
	Amy Anderson (b) (4)	18 Jan 2021 15:47:07
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:51:52

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	21 Jan 2021 17:55:29
User entered empty.	Amy Anderson (b) (4)	18 Jan 2021 15:47:07
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:51:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	21 Jan 2021 17:55:29
User entered empty.	Amy Anderson (b) (4)	18 Jan 2021 15:47:07
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:51:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	21 Jan 2021 17:55:29
User entered empty.	Amy Anderson (b) (4)	18 Jan 2021 15:47:07
	(b) (4)	

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Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:51:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Amy Anderson (b) (4)	21 Jan 2021 17:55:29
	(b) (4)	
	Amy Anderson (b) (4)	18 Jan 2021 15:47:07
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:51:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	21 Jan 2021 17:55:29
User entered empty.	Amy Anderson (b) (4)	18 Jan 2021 15:47:07
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:51:52

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Amy Anderson (b) (4)	21 Jan 2021 17:55:29
	(b) (4)	
	Amy Anderson (b) (4)	18 Jan 2021 15:47:07
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:51:52

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	21 Jan 2021 17:55:29
User entered empty.	Amy Anderson (b) (4)	18 Jan 2021 15:47:07
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:51:52

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Amy Anderson (b) (4)	21 Jan 2021 17:55:29
	(b) (4)	
	Amy Anderson (b) (4)	18 Jan 2021 15:47:07
	(b) (4)	

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:51:52

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Amy Anderson (b) (4)	21 Jan 2021 17:55:29
	(b) (4)	
	Amy Anderson (b) (4)	18 Jan 2021 15:47:07
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:51:52

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Day 15 (Day 15)'	(b) (4) Amy Anderson (b) (4)	18 Jan 2021 15:54:24

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:51:52

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:53:08
User entered '18 Jan 2021'	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:54:24

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:51:52

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:53:10
User entered '0'	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:54:24

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:51:52

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:54:21
User entered '98'	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:54:24

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:51:52

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User entered '%'	System	18 Jan 2021 15:54:24

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:51:52

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:54:23
User entered '97.8' F	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:54:24

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:51:52

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:54:24
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:54:24

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:51:52

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:54:26
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:54:24

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:51:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:54:27
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:54:24

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:51:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:54:29
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:54:24

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:51:52

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:54:31
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:54:24

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:51:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:54:32
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:54:24

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:51:52

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:54:34
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:54:24

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:51:52

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:54:35
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:54:24

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:51:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:54:37
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:54:24

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:51:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:54:39
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:54:24

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:51:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:54:40
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:54:24

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:51:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:54:42
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:54:24

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:51:52

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:54:43
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:54:24

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:51:52

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:54:44
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:54:24

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:51:52

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:54:46
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:54:24

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:51:52

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:54:47
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:54:24

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:51:52

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Day 16 (Day 16)'	(b) (4) Amy Anderson (b) (4)	21 Jan 2021 13:34:37

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:51:52

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '19 Jan 2021'	(b) (4) Amy Anderson (b) (4) (b) (4)	21 Jan 2021 13:34:37

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:51:52

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '0'	(b) (4) Amy Anderson (b) (4) (b) (4)	21 Jan 2021 13:34:37

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:51:52

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '98'	(b) (4) Amy Anderson (b) (4) (b) (4)	21 Jan 2021 13:34:37

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:51:52

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User entered '%'	System	21 Jan 2021 13:34:37

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:51:52

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '97.6' F	(b) (4) Amy Anderson (b) (4) (b) (4)	21 Jan 2021 13:34:37

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:51:52

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	21 Jan 2021 13:34:37

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:51:52

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	21 Jan 2021 13:34:37

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:51:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	21 Jan 2021 13:34:37

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:51:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	21 Jan 2021 13:34:37

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:51:52

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	21 Jan 2021 13:34:37

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:51:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	21 Jan 2021 13:34:37

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:51:52

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	21 Jan 2021 13:34:37

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:51:52

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	21 Jan 2021 13:34:37

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:51:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	21 Jan 2021 13:34:37

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:51:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	21 Jan 2021 13:34:37

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:51:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	21 Jan 2021 13:34:37

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:51:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	21 Jan 2021 13:34:37

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:51:52

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	21 Jan 2021 13:34:37

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:51:52

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	21 Jan 2021 13:34:37

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:51:52

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	21 Jan 2021 13:34:37

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:51:52

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	21 Jan 2021 13:34:37

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:51:52

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Day 17 (Day 17)'	(b) (4) Amy Anderson (b) (4)	21 Jan 2021 13:35:47

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:51:52

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '20 Jan 2021'	(b) (4) Amy Anderson (b) (4) (b) (4)	21 Jan 2021 13:35:47

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:51:52

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '0'	(b) (4) Amy Anderson (b) (4) (b) (4)	21 Jan 2021 13:35:47

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:51:52

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '99'	(b) (4) Amy Anderson (b) (4) (b) (4)	21 Jan 2021 13:35:47

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:51:52

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User entered '%'	System	21 Jan 2021 13:35:47

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:51:52

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '98.2' F	(b) (4) Amy Anderson (b) (4) (b) (4)	21 Jan 2021 13:35:47

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:51:52

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	21 Jan 2021 13:35:47

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:51:52

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	21 Jan 2021 13:35:47

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:51:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	21 Jan 2021 13:35:47

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:51:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	21 Jan 2021 13:35:47

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:51:52

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	21 Jan 2021 13:35:47

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:51:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	21 Jan 2021 13:35:47

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:51:52

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	21 Jan 2021 13:35:47

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:51:52

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	21 Jan 2021 13:35:47

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:51:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	21 Jan 2021 13:35:47

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:51:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	21 Jan 2021 13:35:47

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:51:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	21 Jan 2021 13:35:47

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:51:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	21 Jan 2021 13:35:47

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:51:52

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	21 Jan 2021 13:35:47

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:51:52

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	21 Jan 2021 13:35:47

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:51:52

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	21 Jan 2021 13:35:47

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:51:52

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	21 Jan 2021 13:35:47

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:51:52

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Day 18 (Day 18)'	(b) (4) Amy Anderson (b) (4)	21 Jan 2021 17:56:40

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:51:52

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '21 Jan 2021'	(b) (4) Amy Anderson (b) (4) (b) (4)	21 Jan 2021 17:56:40

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:51:52

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '0'	(b) (4) Amy Anderson (b) (4) (b) (4)	21 Jan 2021 17:56:40

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:51:52

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '97'	(b) (4) Amy Anderson (b) (4) (b) (4)	21 Jan 2021 17:56:40

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:51:52

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
User entered '%'	System	21 Jan 2021 17:56:40

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:51:52

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '98.6' F	(b) (4) Amy Anderson (b) (4) (b) (4)	21 Jan 2021 17:56:40

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:51:52

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	21 Jan 2021 17:56:40

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:51:52

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	21 Jan 2021 17:56:40

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:51:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	21 Jan 2021 17:56:40

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:51:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	21 Jan 2021 17:56:40

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:51:52

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	21 Jan 2021 17:56:40

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:51:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	21 Jan 2021 17:56:40

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:51:52

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	21 Jan 2021 17:56:40

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:51:52

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	21 Jan 2021 17:56:40

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:51:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	21 Jan 2021 17:56:40

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:51:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	21 Jan 2021 17:56:40

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:51:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	21 Jan 2021 17:56:40

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:51:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	21 Jan 2021 17:56:40

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:51:52

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	21 Jan 2021 17:56:40

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:51:52

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	21 Jan 2021 17:56:40

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:51:52

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	21 Jan 2021 17:56:40

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:51:52

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	21 Jan 2021 17:56:40

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Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID Diagnostic Test

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[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:45
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:54:58
User entered '08 Jan 2021'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:12:19

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Form: COVID Diagnostic Test

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[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 12:58:45
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:54:58
User entered 'Yes (Y)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:12:19

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Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:51:52

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 12:58:45
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:54:58
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	14 Jan 2021 09:33:44
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	14 Jan 2021 09:33:27
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 'confirmed' (Site from System).	Amy Anderson (b) (4) (b) (4)	12 Jan 2021 13:03:52
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	12 Jan 2021 13:03:43
User entered 'Yes (Y)' reason for change: Data Entry Error	Amy Anderson (b) (4) (b) (4)	12 Jan 2021 13:03:43
Query 'Data is required. Please complete.' answered with 'results not back' (Site from System).	Amy Anderson (b) (4) (b) (4)	10 Jan 2021 15:05:09
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Jan 2021 15:12:19
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:12:19

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Form: COVID Diagnostic Test

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[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:45
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:54:58
User entered '08 Jan 2021'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:12:19

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Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID Diagnostic Test

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[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:45
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:54:58
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:12:19

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Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:51:52

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:45
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:54:58
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:12:19

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Form: COVID Diagnostic Test

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[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 12:58:45
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:54:58
User entered 'No (N)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:12:19

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Form: COVID Diagnostic Test

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[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:45
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:54:58
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:12:19

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Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID Diagnostic Test

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[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:45
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:54:58
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:12:19

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Form: COVID Diagnostic Test

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[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:58:45
User entered 'I'	System	12 Jan 2021 13:03:43

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Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:51:52

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:59:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:56:15
User entered 'No (N)'	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:57:58

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:51:52

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:59:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:56:15
User entered empty.	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:57:58

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:51:52

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:59:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:56:15
User entered empty.	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:57:58

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[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:59:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:56:15
User entered empty.	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:57:58

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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 12:59:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:56:15
User entered 'No (N)'	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:57:58

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Folder: Covid-19 Assessment 08 Jan 2021

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 12:59:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:56:15
User entered empty.	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:57:58

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Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:59:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:56:15
User entered empty.	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:57:58

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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:59:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:56:15
User entered empty.	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:57:58

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Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:59:00
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:52:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	21 Jan 2021 19:19:22
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	21 Jan 2021 19:19:22
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:56:15
User entered 'No (N)'	Amy Anderson (b) (4)	18 Jan 2021 15:57:58
	(b) (4)	

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:59:00
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:51:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	28 Jan 2021 15:51:50
User entered '08 Jan 2021' reason for change: Data Entry Error	(b) (4)	28 Jan 2021 15:51:50
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:56:15
User entered empty.	Amy Anderson (b) (4)	18 Jan 2021 15:57:58
	(b) (4)	

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Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:51:52

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:59:00
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:51:56
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	28 Jan 2021 15:51:50
User entered '08 Jan 2021' reason for change: Data Entry Error	(b) (4)	28 Jan 2021 15:51:50
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:56:15
User entered empty.	Amy Anderson (b) (4)	18 Jan 2021 15:57:58
	(b) (4)	

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:59:00
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:51:58
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	28 Jan 2021 15:51:50
User entered '93' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	28 Jan 2021 15:51:50
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:56:15
User entered empty.	Amy Anderson (b) (4)	18 Jan 2021 15:57:58
	(b) (4)	

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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 12:59:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:56:15
User entered 'No (N)'	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:57:58

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:59:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:56:15
User entered empty.	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:57:58

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:51:52

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:59:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:56:15
User entered empty.	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:57:58

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:59:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:56:15
User entered empty.	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:57:58

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Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:59:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:56:15
User entered 'No (N)'	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:57:58

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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 12:59:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:56:15
User entered empty.	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:57:58

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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 12:59:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:56:15
User entered 'No (N)'	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:57:58

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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 12:59:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:56:15
User entered empty.	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:57:58

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:59:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:56:15
User entered 'No (N)'	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:57:58

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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 12:59:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:56:15
User entered empty.	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:57:58

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:59:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:56:15
User entered empty.	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:57:58

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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:59:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:56:15
User entered 'No (N)'	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:57:58

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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 12:59:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:56:15
User entered empty.	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:57:58

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:51:52

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:59:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:56:15
User entered empty.	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:57:58

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:51:52

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:59:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:56:15
User entered 'No (N)'	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:57:58

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:51:52

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:59:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:56:15
User entered empty.	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:57:58

US3482286

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:59:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:56:15
User entered empty.	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:57:58

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

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[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:59:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:56:15
User entered 'No (N)'	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:57:58

US3482286

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:59:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:56:15
User entered empty.	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:57:58

US3482286

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:59:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:56:15
User entered empty.	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:57:58

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

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Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:59:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:56:15
User entered 'No (N)'	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:57:58

US3482286

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:59:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:56:15
User entered empty.	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:57:58

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:59:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:56:15
User entered empty.	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:57:58

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

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Generated On: 09 Jun 2021 17:51:52

[Evidence of Shock Requires](#)

[Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:59:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:56:15
User entered 'No (N)'	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:57:58

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:59:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:56:15
User entered empty.	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:57:58

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:59:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:56:15
User entered empty.	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:57:58

US3482286

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Form: Covid-19 Severity Assessment

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[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:59:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:56:15
User entered 'No (N)'	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:57:58

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:59:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:56:15
User entered empty.	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:57:58

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Folder: Covid-19 Assessment 08 Jan 2021

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[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:59:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:56:15
User entered 'No (N)'	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:57:58

US3482286

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:59:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:56:15
User entered empty.	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:57:58

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:51:52

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:59:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:56:15
User entered 'No (N)'	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:57:58

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:59:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:56:15
User entered empty.	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:57:58

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Generated On: 09 Jun 2021 17:51:52

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:59:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:56:15
User entered 'No (N)'	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:57:58

US3482286

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[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:59:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:56:15
User entered empty.	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:57:58

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:51:52

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:59:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:56:15
User entered 'No (N)'	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:57:58

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

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Generated On: 09 Jun 2021 17:51:52

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:59:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:56:15
User entered empty.	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:57:58

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:51:52

[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 12:59:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:56:15
User entered 'No (N)'	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:57:58

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:51:52

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:59:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:56:15
User entered empty.	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:57:58

US3482286

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:51:52

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:59:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:56:15
User entered empty.	Amy Anderson (b) (4) (b) (4)	18 Jan 2021 15:57:58

US3482286

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:51:52

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Amy Anderson (b) (4) (b) (4)	21 Jan 2021 17:58:04

US3482286

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:51:52

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:00:28
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Yes (Y)'	(b) (4) Amy Anderson (b) (4)	21 Jan 2021 17:58:04

US3482286

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:51:52

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:00:29
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 10JAN2021 is recorded under Illness Visit Day 3 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Mar 2021 05:53:21
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 10JAN2021 is recorded under Illness Visit Day 3 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'not missing. look in preclarus. 1F60MH9' (Site from DM).	Amy Anderson (b) (4) (b) (4)	02 Feb 2021 12:49:22
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 10JAN2021 is recorded under Illness Visit Day 3 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 04:35:50
User entered '10 Jan 2021'	Amy Anderson (b) (4) (b) (4)	21 Jan 2021 17:58:04

US3482286

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:51:52

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Amy Anderson (b) (4) (b) (4)	21 Jan 2021 17:58:04

US3482286

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:51:52

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:00:34
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Yes (Y)'	Amy Anderson (b) (4)	21 Jan 2021 17:58:04

US3482286

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:51:52

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:00:35
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 12JAN2021 is recorded under Illness Visit Day 5 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Mar 2021 05:53:25
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 12JAN2021 is recorded under Illness Visit Day 5 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'not missing. look in preclarus. 1F60MH9' (Site from DM).	Amy Anderson (b) (4) (b) (4)	02 Feb 2021 12:49:32
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 12JAN2021 is recorded under Illness Visit Day 5 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 04:35:58
User entered '12 Jan 2021'	Amy Anderson (b) (4) (b) (4)	21 Jan 2021 17:58:04

US3482286

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:51:52

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Amy Anderson (b) (4) (b) (4)	21 Jan 2021 17:58:04

US3482286

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:51:52

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:00:41
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Yes (Y)'	Amy Anderson (b) (4)	21 Jan 2021 17:58:04

US3482286

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:51:52

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:00:43
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 14JAN2021 is recorded under Illness Visit Day 7 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Mar 2021 05:53:28
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 14JAN2021 is recorded under Illness Visit Day 7 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'not missing. look in preclarus. 1F60MH9' (Site from DM).	Amy Anderson (b) (4) (b) (4)	02 Feb 2021 12:49:37
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 14JAN2021 is recorded under Illness Visit Day 7 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 04:36:07
User entered '14 Jan 2021'	Amy Anderson (b) (4) (b) (4)	21 Jan 2021 17:58:04

US3482286

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:51:52

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Amy Anderson (b) (4) (b) (4)	21 Jan 2021 17:58:04

US3482286

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:51:52

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:00:47
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Yes (Y)'	Amy Anderson (b) (4)	21 Jan 2021 17:58:04

US3482286

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:51:52

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:00:49
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16JAN2021 is recorded under Illness Visit Day 9 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Mar 2021 05:53:33
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16JAN2021 is recorded under Illness Visit Day 9 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'not missing. look in preclarus. 1F60MH9' (Site from DM).	Amy Anderson (b) (4) (b) (4)	02 Feb 2021 12:49:44
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16JAN2021 is recorded under Illness Visit Day 9 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 04:36:16
User entered '16 Jan 2021'	Amy Anderson (b) (4) (b) (4)	21 Jan 2021 17:58:04

US3482286

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:51:52

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Amy Anderson (b) (4) (b) (4)	21 Jan 2021 17:58:04

US3482286

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:51:52

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:00:55
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Yes (Y)'	(b) (4) Amy Anderson (b) (4)	21 Jan 2021 17:58:04

US3482286

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:51:52

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:00:57
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 21JAN2021 is recorded under Illness Visit Day 14 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Mar 2021 05:53:36
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 21JAN2021 is recorded under Illness Visit Day 14 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'not missing. look in preclarus. 1F60MH9' (Site from DM).	Amy Anderson (b) (4) (b) (4)	02 Feb 2021 12:49:50
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 21JAN2021 is recorded under Illness Visit Day 14 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 04:39:55
User entered '21 Jan 2021'	Amy Anderson (b) (4) (b) (4)	21 Jan 2021 17:58:04

US3482286

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:51:52

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Amy Anderson (b) (4) (b) (4)	21 Jan 2021 17:58:04

US3482286

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:51:52

Was Saliva Collected?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:01:03
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Yes (Y)' reason for change: Data Entry Error	Amy Anderson (b) (4)	02 Feb 2021 12:50:33
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	22 Jan 2021 10:55:59
Query 'Data is required. Please complete.' answered with 'not yet due' (Site from System).	Amy Anderson (b) (4)	21 Jan 2021 17:58:14
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Jan 2021 17:58:04
User entered empty.	Amy Anderson (b) (4)	21 Jan 2021 17:58:04

US3482286

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:51:52

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:01:05
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '27 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	02 Feb 2021 12:50:33
User entered empty.	(b) (4)	
	Amy Anderson (b) (4)	21 Jan 2021 17:58:04
	(b) (4)	

US3482286

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:51:52

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Amy Anderson (b) (4) (b) (4)	21 Jan 2021 17:58:04

US3482286

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:51:52

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:01:09
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Yes (Y)' reason for change: Data Entry Error	Sarah Bechnak (b) (4)	10 Feb 2021 15:41:48
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	22 Jan 2021 10:56:02
Query 'Data is required. Please complete.' answered with 'not yet due' (Site from System).	Amy Anderson (b) (4)	21 Jan 2021 17:58:25
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Jan 2021 17:58:04
User entered empty.	Amy Anderson (b) (4)	21 Jan 2021 17:58:04

US3482286

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:51:52

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:01:11
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '10 Feb 2021' reason for change: Data Entry Error	(b) (4)	
	Sarah Bechnak (b) (4)	10 Feb 2021 15:41:48
User entered empty.	(b) (4)	
	Amy Anderson (b) (4)	21 Jan 2021 17:58:04
	(b) (4)	

US3482286

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:51:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:39:26
User entered 'Yes (Y)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:07:39

US3482286

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:39:26
User entered '08 Jan 2021'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:07:39

US3482286

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:51:52

[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 17:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:39:26
User entered 'Clinic (Clinic)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:07:39

US3482286

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:51:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:05:06
User entered 'SICKD1'	System	08 Jan 2021 15:07:39

US3482286

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:41:33
User entered 'Yes (Y)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:10:55

US3482286

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:41:35
User entered '08 Jan 2021'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:10:55

US3482286

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:42:00
User entered '08:19'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:10:55

US3482286

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:05:06
User entered '08 Jan 2021 08:19'	System	08 Jan 2021 15:10:55

US3482286

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:42:02
User entered missing code ND - Not Done.	Joy Winters (b) (4)	08 Jan 2021 15:10:55
DataPoint set to visible.	(b) (4) System	08 Jan 2021 15:07:39

US3482286

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:42:04
User entered missing code ND - Not Done.	Joy Winters (b) (4)	08 Jan 2021 15:10:55
DataPoint set to visible.	(b) (4) System	08 Jan 2021 15:07:39

US3482286

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:42:06
User entered '98.9' F	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:10:55

US3482286

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:42:07
User entered 'Oral (Oral)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:10:55

US3482286

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:42:09
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:10:55

US3482286

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:42:14
User entered '80'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:10:55

US3482286

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:05:06
User entered 'bpm'	System	08 Jan 2021 15:10:55

US3482286

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:42:17
User entered '16'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:10:55

US3482286

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:05:06
User entered 'breaths/min'	System	08 Jan 2021 15:10:55

US3482286

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:42:19
User entered '132'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:10:55

US3482286

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:05:06
User entered 'mmHg'	System	08 Jan 2021 15:10:55

US3482286

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:42:21
User entered '80'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:10:55

US3482286

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:05:06
User entered 'mmHg'	System	08 Jan 2021 15:10:55

US3482286

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:05:06

US3482286

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:05:06

US3482286

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:51:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User closed query 'Please complete saliva collection form.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:47:53
Query 'Please complete saliva collection form.' answered with 'ok' (Site from CRA).	Amy Anderson (b) (4) (b) (4)	21 Jan 2021 17:57:11
User opened query 'Please complete saliva collection form.' (Site from CRA).	(b) (4), (b) (6)	20 Jan 2021 20:44:57
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:42:49
User entered 'Yes (Y)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:11:12

US3482286

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:51:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:42:49
User entered '08 Jan 2021'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:11:12

US3482286

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 17:51:52

[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 17:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:42:56
User entered 'Yes (Y)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:11:23

US3482286

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 17:51:52

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:42:56
User entered '08 Jan 2021'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:11:23

US3482286

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:51:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:50
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:53:06
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	10 Feb 2021 15:40:14

US3482286

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:50
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:53:06
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered '10 Feb 2021'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	10 Feb 2021 15:40:14

US3482286

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:51:52

[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 17:09:50
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:53:06
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered 'Clinic (Clinic)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	10 Feb 2021 15:40:14

US3482286

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:51:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:50
User entered 'SICKD28'	System	10 Feb 2021 15:40:14

US3482286

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:50
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:53:10
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	10 Feb 2021 15:40:59

US3482286

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:50
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:53:10
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered '10 Feb 2021'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	10 Feb 2021 15:40:59

US3482286

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:50
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:53:10
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered '09:13'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	10 Feb 2021 15:40:59

US3482286

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:50
User entered '10 Feb 2021 09:13'	System	10 Feb 2021 15:40:59

US3482286

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:50
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:53:10
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered missing code ND - Not Done.	(b) (4) Sarah Bechnak (b) (4)	10 Feb 2021 15:40:59
DataPoint set to visible.	(b) (4) System	10 Feb 2021 15:40:14

US3482286

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:50
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:53:10
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered missing code ND - Not Done.	(b) (4) Sarah Bechnak (b) (4)	10 Feb 2021 15:40:59
DataPoint set to visible.	(b) (4) System	10 Feb 2021 15:40:14

US3482286

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:50
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:53:10
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered '98.4' F	(b) (4) Sarah Bechnak (b) (4) (b) (4)	10 Feb 2021 15:40:59

US3482286

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:50
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:53:10
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered 'Oral (Oral)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	10 Feb 2021 15:40:59

US3482286

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:50
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:53:10
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered empty.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	10 Feb 2021 15:40:59

US3482286

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:50
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:53:10
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered '66'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	10 Feb 2021 15:40:59

US3482286

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:50
User entered 'bpm'	System	10 Feb 2021 15:40:59

US3482286

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:50
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:53:10
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered '16'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	10 Feb 2021 15:40:59

US3482286

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:50
User entered 'breaths/min'	System	10 Feb 2021 15:40:59

US3482286

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:50
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:53:10
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered '127'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	10 Feb 2021 15:40:59

US3482286

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:50
User entered 'mmHg'	System	10 Feb 2021 15:40:59

US3482286

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:50
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:53:10
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered '87'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	10 Feb 2021 15:40:59

US3482286

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:50
User entered 'mmHg'	System	10 Feb 2021 15:40:59

US3482286

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:50

US3482286

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:50

US3482286

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:51:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:50
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:53:25
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	10 Feb 2021 15:41:06

US3482286

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:51:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:50
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:53:25
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered '10 Feb 2021'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	10 Feb 2021 15:41:06

US3482286

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 09 Jun 2021 17:51:52

[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 17:09:50
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:55:44
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	10 Feb 2021 15:41:34

US3482286

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 09 Jun 2021 17:51:52

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:50
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:55:44
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered '10 Feb 2021'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	10 Feb 2021 15:41:34

US3482286

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

Form: Visit Date

Generated On: 09 Jun 2021 17:51:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	10 Feb 2021 15:35:35

US3482286

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

Form: Visit Date

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '10 Feb 2021'	(b) (4) Sarah Bechnak (b) (4)	10 Feb 2021 15:35:35
	(b) (4)	

US3482286

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

Form: Visit Date

Generated On: 09 Jun 2021 17:51:52

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Clinic (Clinic)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	10 Feb 2021 15:35:35

US3482286

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

Form: Visit Date

Generated On: 09 Jun 2021 17:51:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User entered 'UNBLND_DECIDE'	System	10 Feb 2021 15:35:35

US3482286

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

Form: Unblinding

Generated On: 09 Jun 2021 17:51:52

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '10 Feb 2021'	(b) (4) Sarah Bechnak (b) (4)	10 Feb 2021 15:36:30

US3482286

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

Form: Unblinding

Generated On: 09 Jun 2021 17:51:52

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 15:31:15

US3482286

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

Form: Unblinding

Generated On: 09 Jun 2021 17:51:52

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	10 Feb 2021 15:36:30

US3482286

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

Form: Unblinding

Generated On: 09 Jun 2021 17:51:52

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 15:31:15

US3482286

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

Form: Unblinding

Generated On: 09 Jun 2021 17:51:52

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '10 Feb 2021'	(b) (4) Sarah Bechnak (b) (4)	10 Feb 2021 15:36:30

US3482286

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

Form: Unblinding

Generated On: 09 Jun 2021 17:51:52

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Placebo (Placebo)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	10 Feb 2021 15:36:30

US3482286

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

Form: Unblinding

Generated On: 09 Jun 2021 17:51:52

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Placebo (Placebo)'	(b) (4) Sarah Bechnak (b) (4)	10 Feb 2021 15:36:30

US3482286

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

Form: Unblinding

Generated On: 09 Jun 2021 17:51:52

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Placebo (Placebo)'	(b) (4) Sarah Bechnak (b) (4)	10 Feb 2021 15:36:30

US3482286

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

Form: Unblinding

Generated On: 09 Jun 2021 17:51:52

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	10 Feb 2021 15:36:30

US3482286

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

Form: Unblinding

Generated On: 09 Jun 2021 17:51:52

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User entered '1'	System	10 Feb 2021 15:36:30

US3482286

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

Form: Unblinding

Generated On: 09 Jun 2021 17:51:52

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User entered 'I'	System	10 Feb 2021 15:36:30

US3482286

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:51:52

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered missing code ND - Not Done.	(b) (4) Sarah Bechnak (b) (4)	10 Feb 2021 15:37:14

US3482286

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:51:52

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered missing code ND - Not Done.	(b) (4) Sarah Bechnak (b) (4)	10 Feb 2021 15:37:14

US3482286

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:51:52

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User entered empty.	System	10 Feb 2021 15:37:14
DataPoint set to visible.	System	10 Feb 2021 15:36:30

US3482286

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:51:52

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered missing code ND - Not Done.	(b) (4) Sarah Bechnak (b) (4)	10 Feb 2021 15:37:14

US3482286

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:51:52

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered missing code ND - Not Done.	(b) (4) Sarah Bechnak (b) (4)	10 Feb 2021 15:37:14

US3482286

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:51:52

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User entered empty.	System	10 Feb 2021 15:37:14
DataPoint set to visible.	System	10 Feb 2021 15:36:30

US3482286

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User accepted default value 'Pre-Dose (PREDOSE)'	Sarah Bechnak (b) (4) (b) (4)	10 Feb 2021 15:37:14

US3482286

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	10 Feb 2021 15:37:14

US3482286

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '10 Feb 2021'	(b) (4) Sarah Bechnak (b) (4)	10 Feb 2021 15:37:14

US3482286

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '09:13'	(b) (4) Sarah Bechnak (b) (4)	10 Feb 2021 15:37:14

US3482286

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User entered '10 Feb 2021 09:13'	System	10 Feb 2021 15:37:14

US3482286

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '98.4' F	(b) (4) Sarah Bechnak (b) (4)	10 Feb 2021 15:37:14

US3482286

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Oral (Oral)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	10 Feb 2021 15:37:14

US3482286

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	10 Feb 2021 15:37:14

US3482286

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '66'	(b) (4) Sarah Bechnak (b) (4)	10 Feb 2021 15:37:14

US3482286

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User entered 'bpm'	System	10 Feb 2021 15:37:14

US3482286

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '16'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	10 Feb 2021 15:37:14

US3482286

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User entered 'breaths/min'	System	10 Feb 2021 15:37:14

US3482286

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '127'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	10 Feb 2021 15:37:14

US3482286

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User entered 'mmHg'	System	10 Feb 2021 15:37:14

US3482286

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '87'	(b) (4) Sarah Bechnak (b) (4)	10 Feb 2021 15:37:14

US3482286

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User entered 'mmHg'	System	10 Feb 2021 15:37:14

US3482286

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:51:52

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered missing code ND - Not Done.	(b) (4) Sarah Bechnak (b) (4)	10 Feb 2021 15:37:14

US3482286

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:51:52

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered missing code ND - Not Done.	(b) (4) Sarah Bechnak (b) (4)	10 Feb 2021 15:37:14

US3482286

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:51:52

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User entered empty.	System	10 Feb 2021 15:37:14
DataPoint set to visible.	System	10 Feb 2021 15:36:30

US3482286

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User accepted default value 'Post-Dose (POSTDOSE)'	Sarah Bechnak (b) (4) (b) (4)	10 Feb 2021 15:37:14

US3482286

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Feb 2021 15:55:49
User entered 'Yes (Y)' reason for change: Data Entry Error	Sarah Bechnak (b) (4)	10 Feb 2021 15:55:49
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	10 Feb 2021 15:37:14
	Sarah Bechnak (b) (4)	10 Feb 2021 15:37:14
	(b) (4)	

US3482286

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '10 Feb 2021' reason for change: Data Entry Error	(b) (4)	
	Sarah Bechnak (b) (4)	10 Feb 2021 15:55:49
User entered empty.	(b) (4)	
	Sarah Bechnak (b) (4)	10 Feb 2021 15:37:14
	(b) (4)	

US3482286

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '10:45' reason for change: Data Entry Error	(b) (4)	
	Sarah Bechnak (b) (4)	10 Feb 2021 15:55:49
User entered empty.	(b) (4)	
	Sarah Bechnak (b) (4)	10 Feb 2021 15:37:14
	(b) (4)	

US3482286

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User entered '10 Feb 2021 10:45'	System	10 Feb 2021 15:55:49
User entered empty.	System	10 Feb 2021 15:37:14

US3482286

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '98.6' F reason for change: Data Entry Error	(b) (4)	
	Sarah Bechnak (b) (4)	10 Feb 2021 15:55:49
User entered empty.	(b) (4)	
	Sarah Bechnak (b) (4)	10 Feb 2021 15:37:14
	(b) (4)	

US3482286

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	
	Sarah Bechnak (b) (4)	10 Feb 2021 15:55:49
User entered empty.	(b) (4)	
	Sarah Bechnak (b) (4)	10 Feb 2021 15:37:14
	(b) (4)	

US3482286

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	10 Feb 2021 15:37:14

US3482286

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '68' reason for change: Data Entry Error	(b) (4)	
	Sarah Bechnak (b) (4)	10 Feb 2021 15:55:49
User entered empty.	(b) (4)	
	Sarah Bechnak (b) (4)	10 Feb 2021 15:37:14
	(b) (4)	

US3482286

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User entered 'bpm'	System	10 Feb 2021 15:55:49
User entered empty.	System	10 Feb 2021 15:37:14

US3482286

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '16' reason for change: Data Entry Error	(b) (4)	
	Sarah Bechnak (b) (4)	10 Feb 2021 15:55:49
User entered empty.	(b) (4)	
	Sarah Bechnak (b) (4)	10 Feb 2021 15:37:14
	(b) (4)	

US3482286

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User entered 'breaths/min'	System	10 Feb 2021 15:55:49
User entered empty.	System	10 Feb 2021 15:37:14

US3482286

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '138' reason for change: Data Entry Error	(b) (4)	
	Sarah Bechnak (b) (4)	10 Feb 2021 15:55:49
User entered empty.	(b) (4)	
	Sarah Bechnak (b) (4)	10 Feb 2021 15:37:14
	(b) (4)	

US3482286

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User entered 'mmHg'	System	10 Feb 2021 15:55:49
User entered empty.	System	10 Feb 2021 15:37:14

US3482286

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '82' reason for change: Data Entry Error	(b) (4)	
	Sarah Bechnak (b) (4)	10 Feb 2021 15:55:49
User entered empty.	(b) (4)	
	Sarah Bechnak (b) (4)	10 Feb 2021 15:37:14
	(b) (4)	

US3482286

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User entered 'mmHg'	System	10 Feb 2021 15:55:49
User entered empty.	System	10 Feb 2021 15:37:14

US3482286

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:51:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	10 Feb 2021 15:37:21

US3482286

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:51:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '10 Feb 2021'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	10 Feb 2021 15:37:21

US3482286

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

Form: Exposure

Generated On: 09 Jun 2021 17:51:52

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	10 Feb 2021 15:37:41

US3482286

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

Form: Exposure

Generated On: 09 Jun 2021 17:51:52

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	10 Feb 2021 15:37:41

US3482286

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

Form: Exposure

Generated On: 09 Jun 2021 17:51:52

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)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered empty.	Sarah Bechnak (b) (4)	10 Feb 2021 15:37:41

US3482286

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

Form: Exposure

Generated On: 09 Jun 2021 17:51:52

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User entered 'mRNA-1273'	System	10 Feb 2021 15:37:41
DataPoint set to visible.	System	10 Feb 2021 15:36:30

US3482286

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

Form: Exposure

Generated On: 09 Jun 2021 17:51:52

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '10 Feb 2021'	(b) (4) Sarah Bechnak (b) (4)	10 Feb 2021 15:37:41

US3482286

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

Form: Exposure

Generated On: 09 Jun 2021 17:51:52

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '10:13'	(b) (4) Sarah Bechnak (b) (4)	10 Feb 2021 15:37:41

US3482286

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

Form: Exposure

Generated On: 09 Jun 2021 17:51:52

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User entered '10 Feb 2021 10:13'	System	10 Feb 2021 15:37:41

US3482286

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

Form: Exposure

Generated On: 09 Jun 2021 17:51:52

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Left Arm (LEFT ARM)'	(b) (4) Sarah Bechnak (b) (4)	10 Feb 2021 15:37:41

US3482286

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

Form: Exposure

Generated On: 09 Jun 2021 17:51:52

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User entered 'ONCE'	System	10 Feb 2021 15:37:41

US3482286

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

Form: Exposure

Generated On: 09 Jun 2021 17:51:52

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User entered 'INTRAMUSCULAR'	System	10 Feb 2021 15:37:41

US3482286

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:51:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	10 Feb 2021 15:38:02

US3482286

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:51:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '10 Feb 2021'	(b) (4) Sarah Bechnak (b) (4)	10 Feb 2021 15:38:02

US3482286

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:51:52

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '09:52'	(b) (4) Sarah Bechnak (b) (4)	10 Feb 2021 15:38:02

US3482286

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:51:52

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User entered '10 Feb 2021 09:52'	System	10 Feb 2021 15:38:02

US3482286

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:51:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	10 Feb 2021 15:38:26

US3482286

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:51:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '10 Feb 2021'	(b) (4) Sarah Bechnak (b) (4)	10 Feb 2021 15:38:26

US3482286

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:51:52

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '09:55'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	10 Feb 2021 15:38:26

US3482286

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:51:52

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User entered '10 Feb 2021 09:55'	System	10 Feb 2021 15:38:26

US3482286

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

Form: Continuing

Generated On: 09 Jun 2021 17:51:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	10 Feb 2021 15:38:33

US3482286

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

Form: Continuing

Generated On: 09 Jun 2021 17:51:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User entered 'I'	System	10 Feb 2021 15:38:33

US3482286

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:51:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	17 Feb 2021 15:54:11

US3482286

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '17 Feb 2021'	(b) (4) Sarah Bechnak (b) (4)	17 Feb 2021 15:54:11

US3482286

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:51:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sarah Bechnak (b) (4)	17 Feb 2021 15:54:11

US3482286

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:51:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	17 Feb 2021 15:54:11

US3482286

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:51:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	17 Feb 2021 15:54:17

US3482286

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:51:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User entered 'I'	System	17 Feb 2021 15:54:17

US3482286

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:51:52

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User entered '1'	System	17 Feb 2021 15:54:17
DataPoint set to visible.	System	17 Feb 2021 15:54:17

US3482286

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:51:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Yes (Y)'	(b) (4) Amy Anderson (b) (4)	12 Mar 2021 13:17:59

US3482286

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '12 Mar 2021'	(b) (4) Amy Anderson (b) (4)	12 Mar 2021 13:17:59

US3482286

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:51:52

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Clinic (Clinic)'	(b) (4) Amy Anderson (b) (4)	12 Mar 2021 13:17:59

US3482286

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:51:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User entered 'OLD29'	System	12 Mar 2021 13:17:59

US3482286

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User accepted default value 'Pre-Dose (PREDOSE)'	Amy Anderson (b) (4) (b) (4)	12 Mar 2021 13:23:01

US3482286

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Yes (Y)'	(b) (4) Amy Anderson (b) (4)	12 Mar 2021 13:23:01

US3482286

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '12 Mar 2021'	(b) (4) Amy Anderson (b) (4)	12 Mar 2021 13:23:01

US3482286

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '08:10'	(b) (4) Amy Anderson (b) (4)	12 Mar 2021 13:23:01

US3482286

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User entered '12 Mar 2021 08:10'	System	12 Mar 2021 13:23:01

US3482286

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '98.3' F	(b) (4) Amy Anderson (b) (4)	12 Mar 2021 13:23:01

US3482286

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Oral (Oral)'	(b) (4) Amy Anderson (b) (4)	12 Mar 2021 13:23:01

US3482286

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered empty.	(b) (4) Amy Anderson (b) (4)	12 Mar 2021 13:23:01

US3482286

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '77'	(b) (4) Amy Anderson (b) (4)	12 Mar 2021 13:23:01

US3482286

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User entered 'bpm'	System	12 Mar 2021 13:23:01

US3482286

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '14'	(b) (4) Amy Anderson (b) (4)	12 Mar 2021 13:23:01

US3482286

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User entered 'breaths/min'	System	12 Mar 2021 13:23:01

US3482286

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '135'	(b) (4) Amy Anderson (b) (4)	12 Mar 2021 13:23:01

US3482286

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User entered 'mmHg'	System	12 Mar 2021 13:23:01

US3482286

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '82'	(b) (4) Amy Anderson (b) (4)	12 Mar 2021 13:23:01

US3482286

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:51:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User entered 'mmHg'	System	12 Mar 2021 13:23:01

US3482286

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User accepted default value 'Post-Dose (POSTDOSE)'	Amy Anderson (b) (4) (b) (4)	12 Mar 2021 13:23:01

US3482286

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Mar 2021 14:25:03
User entered 'Yes (Y)' reason for change: Data Entry Error	Amy Anderson (b) (4)	12 Mar 2021 14:25:03
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	12 Mar 2021 13:23:01
	Amy Anderson (b) (4)	12 Mar 2021 13:23:01
	(b) (4)	

US3482286

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '12 Mar 2021' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	12 Mar 2021 14:25:03
User entered empty.	(b) (4)	
	Amy Anderson (b) (4)	12 Mar 2021 13:23:01
	(b) (4)	

US3482286

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '09:00' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	12 Mar 2021 14:25:03
User entered empty.	(b) (4)	
	Amy Anderson (b) (4)	12 Mar 2021 13:23:01
	(b) (4)	

US3482286

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User entered '12 Mar 2021 09:00'	System	12 Mar 2021 14:25:03
User entered empty.	System	12 Mar 2021 13:23:01

US3482286

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '97.5' F reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	12 Mar 2021 14:25:03
User entered empty.	(b) (4)	
	Amy Anderson (b) (4)	12 Mar 2021 13:23:01
	(b) (4)	

US3482286

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	12 Mar 2021 14:25:03
User entered empty.	(b) (4)	
	Amy Anderson (b) (4)	12 Mar 2021 13:23:01
	(b) (4)	

US3482286

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered empty.	(b) (4) Amy Anderson (b) (4)	12 Mar 2021 13:23:01

US3482286

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '69' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	12 Mar 2021 14:25:03
User entered empty.	(b) (4)	
	Amy Anderson (b) (4)	12 Mar 2021 13:23:01
	(b) (4)	

US3482286

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User entered 'bpm'	System	12 Mar 2021 14:25:03
User entered empty.	System	12 Mar 2021 13:23:01

US3482286

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '12' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	12 Mar 2021 14:25:03
User entered empty.	(b) (4)	
	Amy Anderson (b) (4)	12 Mar 2021 13:23:01
	(b) (4)	

US3482286

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User entered 'breaths/min'	System	12 Mar 2021 14:25:03
User entered empty.	System	12 Mar 2021 13:23:01

US3482286

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '137' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	12 Mar 2021 14:25:03
User entered empty.	(b) (4)	
	Amy Anderson (b) (4)	12 Mar 2021 13:23:01
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User entered 'mmHg'	System	12 Mar 2021 14:25:03
User entered empty.	System	12 Mar 2021 13:23:01

US3482286

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '85' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	12 Mar 2021 14:25:03
User entered empty.	(b) (4)	
	Amy Anderson (b) (4)	12 Mar 2021 13:23:01
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:51:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User entered 'mmHg'	System	12 Mar 2021 14:25:03
User entered empty.	System	12 Mar 2021 13:23:01

US3482286

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:51:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Yes (Y)'	(b) (4) Amy Anderson (b) (4)	12 Mar 2021 13:18:13

US3482286

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:51:52

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '12 Mar 2021'	(b) (4) Amy Anderson (b) (4)	12 Mar 2021 13:18:13

US3482286

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:51:52

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Yes (Y)'	(b) (4) Amy Anderson (b) (4)	12 Mar 2021 14:25:35

US3482286

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:51:52

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered empty.	(b) (4) Amy Anderson (b) (4)	12 Mar 2021 14:25:35

US3482286

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:51:52

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)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered empty.	Amy Anderson (b) (4)	12 Mar 2021 14:25:35

US3482286

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:51:52

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User entered 'mRNA-1273'	System	12 Mar 2021 14:25:35
DataPoint set to visible.	System	17 Feb 2021 15:54:17

US3482286

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:51:52

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '12 Mar 2021'	(b) (4) Amy Anderson (b) (4)	12 Mar 2021 14:25:35

US3482286

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:51:52

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered '08:30'	Amy Anderson (b) (4)	12 Mar 2021 14:25:35

US3482286

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:51:52

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User entered '12 Mar 2021 08:30'	System	12 Mar 2021 14:25:35

US3482286

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:51:52

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Left Arm (LEFT ARM)'	Amy Anderson (b) (4)	12 Mar 2021 14:25:35

US3482286

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:51:52

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User entered 'ONCE'	System	12 Mar 2021 14:25:35

US3482286

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:51:52

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User entered 'INTRAMUSCULAR'	System	12 Mar 2021 14:25:35

US3482286

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:51:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Yes (Y)'	(b) (4) Amy Anderson (b) (4)	12 Mar 2021 13:18:19

US3482286

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:51:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User entered 'I'	System	12 Mar 2021 13:18:19

US3482286

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:51:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Yes (Y)'	(b) (4) Amy Anderson (b) (4)	18 Mar 2021 15:24:29

US3482286

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:51:52

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User closed query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	
Query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	19 Mar 2021 20:30:26
User entered '19 Mar 2021' reason for change: Data Entry Error	System	19 Mar 2021 20:30:26
User opened query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	Amy Anderson (b) (4)	19 Mar 2021 20:30:26
User entered '18 Mar 2021'	(b) (4)	
	System	18 Mar 2021 15:24:29
	Amy Anderson (b) (4)	18 Mar 2021 15:24:29
	(b) (4)	

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Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:51:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Amy Anderson (b) (4)	18 Mar 2021 15:24:29

US3482286

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:51:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered empty.	(b) (4) Amy Anderson (b) (4)	18 Mar 2021 15:24:29

US3482286

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:51:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:34:52
User entered 'Yes (Y)'	(b) (4) Amy Anderson (b) (4)	18 Mar 2021 15:24:37

US3482286

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:51:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:10
User entered 'I'	System	18 Mar 2021 15:24:37

US3482286

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:51:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:24
	(b) (4)	
User entered 'Yes (Y)'	Sarah Bechnak (b) (4)	07 Apr 2021 13:16:00
	(b) (4)	

US3482286

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:24
	(b) (4)	
User entered '7 Apr 2021'	Sarah Bechnak (b) (4)	07 Apr 2021 13:16:00
	(b) (4)	

US3482286

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:24
User entered 'Clinic (Clinic)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	07 Apr 2021 13:16:00

US3482286

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:51:52

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	07 Apr 2021 13:16:00

US3482286

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:24
	(b) (4)	
User entered 'No (N)'	Sarah Bechnak (b) (4)	07 Apr 2021 13:16:13
	(b) (4)	

US3482286

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:24
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	07 Apr 2021 13:16:13
	(b) (4)	

US3482286

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:24
	(b) (4)	
User entered empty.	Sarah Bechnak (b) (4)	07 Apr 2021 13:16:13
	(b) (4)	

US3482286

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 13:16:13

US3482286

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:24
	(b) (4)	
User entered empty.	Sarah Bechnak (b) (4)	07 Apr 2021 13:16:13
	(b) (4)	

US3482286

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:24
	(b) (4)	
User entered empty.	Sarah Bechnak (b) (4)	07 Apr 2021 13:16:13
	(b) (4)	

US3482286

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:24
	(b) (4)	
User entered empty.	Sarah Bechnak (b) (4)	07 Apr 2021 13:16:13
	(b) (4)	

US3482286

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:24
	(b) (4)	
User entered empty.	Sarah Bechnak (b) (4)	07 Apr 2021 13:16:13
	(b) (4)	

US3482286

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 13:16:13

US3482286

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:24
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	07 Apr 2021 13:16:13
	(b) (4)	

US3482286

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 13:16:13

US3482286

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:24
	(b) (4)	
User entered empty.	Sarah Bechnak (b) (4)	07 Apr 2021 13:16:13
	(b) (4)	

US3482286

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 13:16:13

US3482286

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:24
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	07 Apr 2021 13:16:13
	(b) (4)	

US3482286

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:51:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 13:16:13

US3482286

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:51:52

Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:24
	(b) (4)	
User entered 'No (N)'	Sarah Bechnak (b) (4)	07 Apr 2021 13:16:06
	(b) (4)	

US3482286

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:51:52

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:24
	(b) (4)	
User entered empty.	Sarah Bechnak (b) (4)	07 Apr 2021 13:16:06
	(b) (4)	

US3482286

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:51:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:24
	(b) (4)	
User entered 'Yes (Y)'	Sarah Bechnak (b) (4)	07 Apr 2021 13:17:57
	(b) (4)	

US3482286

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:51:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:24
	(b) (4)	
User entered '7 Apr 2021'	Sarah Bechnak (b) (4)	07 Apr 2021 13:17:57
	(b) (4)	

US3482286

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:51:52

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:24
	(b) (4)	
User entered '08:40'	Sarah Bechnak (b) (4)	07 Apr 2021 13:17:57
	(b) (4)	

US3482286

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:51:52

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '7 Apr 2021 08:40'	System	07 Apr 2021 13:17:57

US3482286

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:51:52

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:34:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:14:15
User entered 'Yes (Y)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 16:19:21

US3482286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:51:52

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:04:53
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:45:05
User entered	System	03 Feb 2021 21:44:59
'USA-US106-2021-mRNA-1273-P301000010'		
User entered 'New'	(b) (4), (b) (6)	03 Feb 2021 21:44:59

US3482286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:51:52

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 18:14:03
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)	12 Jan 2021 13:05:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	12 Jan 2021 13:05:52
Data point term sent to Coder	System	12 Jan 2021 13:04:38
Coding entries removed.	Amy Anderson (b) (4)	12 Jan 2021 13:04:19
	(b) (4)	
User entered 'covid-19' reason for change: New Information	Amy Anderson (b) (4)	12 Jan 2021 13:04:19
	(b) (4)	
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: General signs and symptoms NEC, PT: Influenza like illness, LLT: Flu-like illness - version MedDRA\23.0.	Coder Import (b) (4)	08 Jan 2021 16:22:40
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	08 Jan 2021 16:22:40
	(b) (4)	
Data point term sent to Coder	System	08 Jan 2021 16:21:36
User entered 'Flu-like illness'	Joy Winters (b) (4)	08 Jan 2021 16:21:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:51:52

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:14:03
User entered 'Yes (Y)' reason for change: Data Entry Error	Michele McCullough (b) (4)	15 Jan 2021 16:28:15
User entered 'No (N)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 16:21:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:51:52

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:04:24
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:52
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 14:27:46
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Jan 2021 14:27:46
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 18:14:03
User entered 'Yes (Y)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 16:21:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:51:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:04:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:52
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 14:27:46
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	28 Jan 2021 14:27:46
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 18:14:03
User entered 'No (N)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 16:21:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:51:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 18:14:03
User entered '04 Jan 2021'	Joy Winters (b) (4)	08 Jan 2021 16:21:11
	(b) (4)	

US3482286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:51:52

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 18:14:03
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 16:21:11
	(b) (4)	

US3482286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:51:52

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Jan 2021 16:21:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:51:52

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:04:32
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:52
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	22 Jan 2021 15:53:56
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	22 Jan 2021 15:53:56
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 18:14:03
User entered 'Yes (Y)'	Joy Winters (b) (4)	08 Jan 2021 16:21:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:51:52

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:04:34
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:52
DataPoint Un-verified.	Amy Anderson (b) (4)	22 Jan 2021 15:53:56
User entered '14 Jan 2021' reason for change: Data Entry Error	Amy Anderson (b) (4)	22 Jan 2021 15:53:56
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 18:14:03
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 16:21:11

US3482286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:51:52

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 18:14:03
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 16:21:11
	(b) (4)	

US3482286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:51:52

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Jan 2021 16:21:11

US3482286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:51:52

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:04:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:52
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 14:27:46
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: New Information	(b) (4), (b) (6)	28 Jan 2021 14:27:46
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 18:14:03
User entered 'Grade 1/Mild (Grade 1/Mild)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 16:21:11

US3482286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:51:52

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:04:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:52
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:04:15
User closed query 'Is the adverse event serious is No, System but seriousness criteria is provided. Please correct.' (Site from System).		28 Jan 2021 14:31:30
DataPoint Un-verified.	(b) (4), (b) (6)	28 Jan 2021 14:31:30
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Jan 2021 14:31:30
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	28 Jan 2021 14:27:46
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 18:14:03
User entered 'No (N)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 16:21:11

US3482286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:51:52

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 18:14:03
User entered '0'	Joy Winters (b) (4)	08 Jan 2021 16:21:11
	(b) (4)	

US3482286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:51:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 18:14:03
User entered '0'	Joy Winters (b) (4)	08 Jan 2021 16:21:11
	(b) (4)	

US3482286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:51:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 18:14:03
User entered '0'	Joy Winters (b) (4)	08 Jan 2021 16:21:11
	(b) (4)	

US3482286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:51:52

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:14:03
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 16:21:11

US3482286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:51:52

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 18:14:03
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 16:21:11
	(b) (4)	

US3482286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:51:52

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 18:14:03
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 16:21:11
	(b) (4)	

US3482286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:51:52

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 18:14:03
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 16:21:11
	(b) (4)	

US3482286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:51:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 18:14:03
User entered '0'	Joy Winters (b) (4)	08 Jan 2021 16:21:11
	(b) (4)	

US3482286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:51:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 18:14:03
User entered '0'	Joy Winters (b) (4)	08 Jan 2021 16:21:11
	(b) (4)	

US3482286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:51:52

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:04:44
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:52
User entered '0' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:04:15
DataPoint Un-verified.	(b) (4), (b) (6)	28 Jan 2021 14:27:46
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Jan 2021 14:27:46
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 18:14:03
User entered '0'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 16:21:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:51:52

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 18:14:03
User entered 'Not Related (NOT RELATED)'	Joy Winters (b) (4)	08 Jan 2021 16:21:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:51:52

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 18:14:03
User entered 'Not Related (NOT RELATED)'	Joy Winters (b) (4)	08 Jan 2021 16:21:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:51:52

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:14:03
User entered 'Not Applicable (NOT APPLICABLE)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 16:21:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:51:52

None

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 18:14:03
User entered '0'	Joy Winters (b) (4)	08 Jan 2021 16:21:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:51:52

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:52
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:31:51
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'added covid-19 diagnosis to con med- motrin' (Site from DM).	Amy Anderson (b) (4) (b) (4)	08 Feb 2021 16:09:19
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 07:16:41
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 18:14:03
User entered 'I'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 16:21:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:51:52

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 18:14:03
User entered '0'	Joy Winters (b) (4)	08 Jan 2021 16:21:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:51:52

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:04:47
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:52
DataPoint Un-verified.	Amy Anderson (b) (4)	22 Jan 2021 15:53:56
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Amy Anderson (b) (4)	22 Jan 2021 15:53:56
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 18:14:03
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Joy Winters (b) (4)	08 Jan 2021 16:21:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:51:52

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:14:03
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 16:21:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:51:52

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:04:48
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:52
User closed query 'PV Query: Per the narrative, it was noted the subject had mild COVID symptoms per the symptom log, however, the symptom log noted severe fatigue, muscle aches, and body aches. Please update or clarify.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:35:39
User closed query 'PV Query: Per the narrative, it was noted that the subject had 2 instances with pulse ox meeting severe criteria of \leq 93%, however, this was only recorded on 08 Jan 2021. Please provide the additional instance this occurred.' (Site from Safety).	(b) (4), (b) (6)	05 Mar 2021 15:35:37
Query 'PV Query: Per the narrative, it was noted that the subject had 2 instances with pulse ox meeting severe criteria of \leq 93%, however, this was only recorded on 08 Jan 2021. Please provide the additional instance this occurred.' answered with 'Updated narrative to remove the mild term.' (Site from Safety).	Amy Anderson (b) (4) (b) (4)	03 Mar 2021 13:02:06
Query 'PV Query: Per the narrative, it was noted the subject had mild COVID symptoms per the symptom log, however, the symptom log noted severe fatigue, muscle aches, and body aches. Please update or clarify.' answered with 'updated narrative by removing "mild" since some symptoms were graded as severe and lower pulse oX readings.' (Site from Safety).	Amy Anderson (b) (4) (b) (4)	03 Mar 2021 13:01:20
User entered 'PARTICIPANT WITH COVID SX AS PER SX LOG; HAD 2 INSTANCES WITH PULSE OX MEETING "SEVERE" CRITERIA PER PROTOCOL (SPO2 \leq 93%) .' reason for change: Per Query Resolution	Amy Anderson (b) (4) (b) (4)	03 Mar 2021 13:00:34
User opened query 'PV Query: Per the narrative, it was noted that the subject had 2 instances with pulse ox meeting severe criteria of \leq 93%, however, this was only recorded on 08 Jan 2021. Please provide the additional instance this occurred.' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 17:32:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:51:52

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Per the narrative, it was noted the subject had mild COVID symptoms per the symptom log, however, the symptom log noted severe fatigue, muscle aches, and body aches. Please update or clarify.' (Site from Safety). DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 17:32:10
	(b) (4), (b) (6)	28 Jan 2021 14:27:46
User entered 'Participant with mild COVID sx as per sx log, but had 2 instances with pulse ox meeting "severe" criteria per protocol (spO2 <= 93%) .' reason for change: New Information DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 14:27:46
	(b) (4), (b) (6)	20 Jan 2021 18:14:03
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 16:21:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:51:52

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	28 Jan 2021 15:04:15
User entered '1'	System	28 Jan 2021 14:31:30
User entered '0'	System	08 Jan 2021 16:21:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:51:52

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	15 Jan 2021 16:28:15
User entered '0'	System	08 Jan 2021 16:21:11

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:51:52

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:34:25
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:02:13
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered 'Yes (Y)'	Joy Winters (b) (4)	08 Jan 2021 15:28:57

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:51:52

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:03:27
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: MOTRIN [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Feb 2021 10:09:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	09 Feb 2021 10:09:45
Data point term sent to Coder Coding entries removed.	System Amy Anderson (b) (4)	08 Feb 2021 16:08:27 08 Feb 2021 16:08:13
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: MOTRIN [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Jan 2021 15:47:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Jan 2021 15:47:42
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: MOTRIN [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Jan 2021 15:32:41

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:51:52

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	08 Jan 2021 15:32:41
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	08 Jan 2021 15:32:18
User entered 'Motrin'	Joy Winters (b) (4)	08 Jan 2021 15:31:35
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:51:52

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:03:27
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered 'No (N)'	Joy Winters (b) (4)	08 Jan 2021 15:31:35

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:51:52

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:03:27
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered 'BODY ACHES related to COVID-19'	(b) (4)	
reason for change: Data Entry Error	Amy Anderson (b) (4)	08 Feb 2021 16:08:13
User entered 'Body Aches'	(b) (4)	
	Joy Winters (b) (4)	08 Jan 2021 15:31:35
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:51:52

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:03:27
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered '200'	Joy Winters (b) (4)	08 Jan 2021 15:31:35

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:51:52

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:03:27
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered 'mg (mg)'	Joy Winters (b) (4)	08 Jan 2021 15:31:35

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:51:52

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:03:27
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:31:35

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:51:52

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:03:27
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered 'as needed (PRN)'	Joy Winters (b) (4)	08 Jan 2021 15:31:35

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:51:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:03:27
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:31:35

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:51:52

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:03:27
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered 'Oral (ORAL)'	Joy Winters (b) (4)	08 Jan 2021 15:31:35

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:51:52

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:03:27
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:31:35

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:51:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:03:27
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered '04 Jan 2021'	Joy Winters (b) (4)	08 Jan 2021 15:31:35

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:51:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:03:27
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered '0'	Joy Winters (b) (4)	08 Jan 2021 15:31:35

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:51:52

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:03:27
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered 'No (N)'	Joy Winters (b) (4)	08 Jan 2021 15:31:35

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:51:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:03:27
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered '06 Jan 2021'	Joy Winters (b) (4)	08 Jan 2021 15:31:35

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:51:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:03:27
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol (related to COVID 19). Review and update entry as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:26:07
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol (related to COVID 19). Review and update entry as appropriate. ' answered with 'changed to no' (Site from DM).	Amy Anderson (b) (4) (b) (4)	03 Mar 2021 13:03:00
User entered 'No (N)' reason for change: Data Entry Error	Amy Anderson (b) (4) (b) (4)	03 Mar 2021 13:02:50
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol (related to COVID 19). Review and update entry as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 07:58:51
User entered 'Yes (Y)' reason for change: Data Entry Error	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:39:35
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Jan 2021 15:31:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Jan 2021 15:31:44
User entered 'No (N)' reason for change: Data Entry Error	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:31:44
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Jan 2021 15:31:35
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:31:35

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:51:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Jan 2021 15:31:35

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:51:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Jan 2021 15:31:35

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:51:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Jan 2021 15:31:35

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:51:52

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:06:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Jan 2021 15:37:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Jan 2021 15:37:41
Data point term sent to Coder	System	08 Jan 2021 15:37:21
User entered 'Vitamin D'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:37:14

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:51:52

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:06:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User closed query 'Per DM CLR: Please review response as supplements/vitamins are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Please review response as supplements/vitamins are considered as prophylaxis. Update as appropriate. ' answered with 'updated per query' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 22:00:27
Query 'Per DM CLR: Please review response as supplements/vitamins are considered as prophylaxis. Update as appropriate. ' answered with 'updated per query' (Site from DM).	Amy Anderson (b) (4)	03 Mar 2021 13:03:41
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per DM CLR: Please review response as supplements/vitamins are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 08:00:34
User entered 'No (N)'	Joy Winters (b) (4)	08 Jan 2021 15:37:14
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:51:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:06:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered 'Supplementation'	Joy Winters (b) (4)	08 Jan 2021 15:37:14

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:51:52

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:06:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered 'UNK'	Joy Winters (b) (4)	08 Jan 2021 15:37:14

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:51:52

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:06:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered 'Other (OTHER)'	Joy Winters (b) (4)	08 Jan 2021 15:37:14

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:51:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:06:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered 'UNK'	Joy Winters (b) (4)	08 Jan 2021 15:37:14

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:51:52

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:06:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered 'once daily (QD)'	Joy Winters (b) (4)	08 Jan 2021 15:37:14

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:51:52

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:06:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:37:14

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:51:52

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:06:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered 'Oral (ORAL)'	Joy Winters (b) (4)	08 Jan 2021 15:37:14

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:51:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:06:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:37:14

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:51:52

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:06:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered '04 Jan 2021'	Joy Winters (b) (4)	08 Jan 2021 15:37:14

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:51:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:06:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered '0'	Joy Winters (b) (4)	08 Jan 2021 15:37:14

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:51:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:06:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered 'No (N)' reason for change: New Information	(b) (4) Sarah Bechnak (b) (4)	10 Feb 2021 15:39:52
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	08 Jan 2021 15:59:41
User entered 'No (N)'	(b) (4) Joy Winters (b) (4)	08 Jan 2021 15:37:14

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:51:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:06:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered '28 Jan 2021' reason for change: New Information	(b) (4)	
	Sarah Bechnak (b) (4)	10 Feb 2021 15:39:52
	(b) (4)	
User entered empty; reason for change Data Entry Error	Joy Winters (b) (4)	08 Jan 2021 15:59:41
	(b) (4)	
User entered '06 Jan 2021'	Joy Winters (b) (4)	08 Jan 2021 15:37:14
	(b) (4)	

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:51:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:06:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:22:19
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update as appropriate. Otherwise, provide clarification.' answered with 'updated per query' (Site from DM).	Amy Anderson (b) (4) (b) (4)	03 Mar 2021 13:03:50
User entered 'No (N)' reason for change: Data Entry Error	Amy Anderson (b) (4) (b) (4)	03 Mar 2021 13:03:33
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 08:00:53
User entered 'Yes (Y)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:37:14

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:51:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:06:16
User entered '1'	System	08 Jan 2021 15:37:14

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:51:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:06:16
User entered '1'	System	08 Jan 2021 15:37:14

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:51:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:06:16
User entered '804 (804)'	System	08 Jan 2021 15:37:14

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:51:52

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:05:49
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Jan 2021 15:57:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Jan 2021 15:57:42
Data point term sent to Coder	System	08 Jan 2021 15:42:22
User entered 'ViTAMIN C' reason for change: Data Entry Error	Joy Winters (b) (4)	08 Jan 2021 15:42:06
User entered 'Vtamin C'	Joy Winters (b) (4)	08 Jan 2021 15:41:26

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:51:52

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:05:49
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User closed query 'Per DM CLR: Please review response as supplements/vitamins are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Mar 2021 21:37:18
Query 'Per DM CLR: Please review response as supplements/vitamins are considered as prophylaxis. Update as appropriate. ' answered with 'updated per query' (Site from DM).	Amy Anderson (b) (4) (b) (4)	03 Mar 2021 13:04:44
User entered 'Yes (Y)' reason for change: Data Entry Error	Amy Anderson (b) (4) (b) (4)	03 Mar 2021 13:04:29
User opened query 'Per DM CLR: Please review response as supplements/vitamins are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 07:59:40
User entered 'No (N)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:41:26

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:51:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:05:49
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered 'Supplementation'	Joy Winters (b) (4)	08 Jan 2021 15:41:26

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:51:52

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:05:49
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered 'UNK'	Joy Winters (b) (4)	08 Jan 2021 15:41:26

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:51:52

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:05:49
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered 'Other (OTHER)'	Joy Winters (b) (4)	08 Jan 2021 15:41:26

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:51:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:05:49
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered 'UNK'	Joy Winters (b) (4)	08 Jan 2021 15:41:26

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:51:52

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:05:49
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered 'once daily (QD)'	Joy Winters (b) (4)	08 Jan 2021 15:41:26

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:51:52

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:05:49
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:41:26

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:51:52

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:05:49
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered 'Oral (ORAL)'	Joy Winters (b) (4)	08 Jan 2021 15:41:26

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:51:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:05:49
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:41:26

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:51:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:05:49
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered '04 Jan 2021'	Joy Winters (b) (4)	08 Jan 2021 15:41:26

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:51:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:05:49
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered '0'	Joy Winters (b) (4)	08 Jan 2021 15:41:26

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:51:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:05:49
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Sarah Bechnak (b) (4)	10 Feb 2021 15:39:11
User entered 'Yes (Y)'	(b) (4)	
	Joy Winters (b) (4)	08 Jan 2021 15:41:26
	(b) (4)	

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:51:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:05:49
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered '28 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Sarah Bechnak (b) (4)	10 Feb 2021 15:39:11
User entered empty.	(b) (4)	
	Joy Winters (b) (4)	08 Jan 2021 15:41:26
	(b) (4)	

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:51:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:05:49
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:25:31
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update as appropriate. Otherwise, provide clarification.' answered with 'updated per query' (Site from DM).	Amy Anderson (b) (4) (b) (4)	03 Mar 2021 13:04:57
User entered 'No (N)' reason for change: Data Entry Error	Amy Anderson (b) (4) (b) (4)	03 Mar 2021 13:04:29
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 07:59:55
User entered 'Yes (Y)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:41:26

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:51:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:05:49
User entered '1'	System	08 Jan 2021 15:41:26

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:51:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:05:49
User entered '1'	System	08 Jan 2021 15:41:26

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:51:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:05:49
User entered '804 (804)'	System	08 Jan 2021 15:41:26

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:51:52

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:05:41
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: ZINC, PRODUCT: ZINC - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	08 Jan 2021 15:46:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Jan 2021 15:46:42
Data point term sent to Coder	System	08 Jan 2021 15:45:24
User entered 'Zinc'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:44:28

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:51:52

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:05:41
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User closed query 'Per DM CLR: Please review response as supplements are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Mar 2021 22:00:59
Query 'Per DM CLR: Please review response as supplements are considered as prophylaxis. Update as appropriate. ' answered with 'updated per query' (Site from DM).	Amy Anderson (b) (4) (b) (4)	03 Mar 2021 13:05:31
User entered 'Yes (Y)' reason for change: Data Entry Error	Amy Anderson (b) (4) (b) (4)	03 Mar 2021 13:05:23
User opened query 'Per DM CLR: Please review response as supplements are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 08:01:14
User entered 'No (N)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:44:28

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:51:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:05:41
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered 'Supplementation'	Joy Winters (b) (4)	08 Jan 2021 15:44:28

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:51:52

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:05:41
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered 'UNK'	Joy Winters (b) (4)	08 Jan 2021 15:44:28

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:51:52

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:05:41
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered 'Other (OTHER)'	Joy Winters (b) (4)	08 Jan 2021 15:44:28

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:51:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:05:41
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered 'UNK'	Joy Winters (b) (4)	08 Jan 2021 15:44:28

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:51:52

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:05:41
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered 'once daily (QD)'	Joy Winters (b) (4)	08 Jan 2021 15:44:28

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:51:52

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:05:41
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:44:28

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:51:52

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:05:41
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered 'Oral (ORAL)'	Joy Winters (b) (4)	08 Jan 2021 15:44:28

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:51:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:05:41
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 15:44:28

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:51:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:05:41
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered '04 Jan 2021'	Joy Winters (b) (4)	08 Jan 2021 15:44:28

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:51:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:05:41
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered '0'	Joy Winters (b) (4)	08 Jan 2021 15:44:28

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:51:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:05:41
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered 'No (N)' reason for change: New Information	(b) (4) Sarah Bechnak (b) (4)	10 Feb 2021 15:39:29
User entered 'Yes (Y)'	(b) (4) Joy Winters (b) (4)	08 Jan 2021 15:44:28

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:51:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:05:41
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered '28 Jan 2021' reason for change: New Information	(b) (4)	
	Sarah Bechnak (b) (4)	10 Feb 2021 15:39:29
User entered empty.	(b) (4)	
	Joy Winters (b) (4)	08 Jan 2021 15:44:28
	(b) (4)	

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:51:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:05:41
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:20:38
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update as appropriate. Otherwise, provide clarification. ' answered with 'updated per query' (Site from DM).	Amy Anderson (b) (4) (b) (4)	03 Mar 2021 13:05:39
User entered 'No (N)' reason for change: Data Entry Error	Amy Anderson (b) (4) (b) (4)	03 Mar 2021 13:05:23
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 08:01:23
User entered 'Yes (Y)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 15:44:28

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:51:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:05:41
User entered '1'	System	08 Jan 2021 15:44:28

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:51:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:05:41
User entered '1'	System	08 Jan 2021 15:44:28

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:51:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:05:41
User entered '804 (804)'	System	08 Jan 2021 15:44:28

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:51:52

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:12:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:03:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: MOTRIN [IBUPROFEN] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	09 Feb 2021 10:09:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Feb 2021 10:09:45
Data point term sent to Coder	System	08 Feb 2021 16:14:38
User entered 'motrin'	Amy Anderson (b) (4) (b) (4)	08 Feb 2021 16:14:33

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:51:52

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:12:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:03:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered 'No (N)'	(b) (4) Amy Anderson (b) (4) (b) (4)	08 Feb 2021 16:14:33

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:51:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:12:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:03:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered 'Body aches related to covid-19'	Amy Anderson (b) (4)	08 Feb 2021 16:14:33

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:51:52

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:12:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:03:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered '200'	(b) (4) Amy Anderson (b) (4) (b) (4)	08 Feb 2021 16:14:33

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:51:52

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:12:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:03:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered 'mg (mg)'	(b) (4) Amy Anderson (b) (4) (b) (4)	08 Feb 2021 16:14:33

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:51:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:12:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:03:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered empty.	Amy Anderson (b) (4)	08 Feb 2021 16:14:33

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:51:52

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:12:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:03:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered 'as needed (PRN)'	(b) (4) Amy Anderson (b) (4) (b) (4)	08 Feb 2021 16:14:33

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:51:52

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:12:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:03:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered empty.	(b) (4) Amy Anderson (b) (4) (b) (4)	08 Feb 2021 16:14:33

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:51:52

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:12:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:03:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered 'Oral (ORAL)'	(b) (4) Amy Anderson (b) (4) (b) (4)	08 Feb 2021 16:14:33

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:51:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:12:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:03:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered empty.	(b) (4) Amy Anderson (b) (4) (b) (4)	08 Feb 2021 16:14:33

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:51:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:12:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:03:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered '10 Jan 2021'	(b) (4) Amy Anderson (b) (4) (b) (4)	08 Feb 2021 16:14:33

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:51:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:12:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:03:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered '0'	(b) (4) Amy Anderson (b) (4) (b) (4)	08 Feb 2021 16:14:33

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:51:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:12:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:03:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered 'No (N)'	(b) (4) Amy Anderson (b) (4) (b) (4)	08 Feb 2021 16:14:33

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:51:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:12:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:03:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered '15 Jan 2021'	(b) (4) Amy Anderson (b) (4) (b) (4)	08 Feb 2021 16:14:33

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:51:52

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:12:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:03:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol (related to COVID 19). Review and update entry as appropriate.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:23:00
' (Site from DM).		
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol (related to COVID 19). Review and update entry as appropriate.	Amy Anderson (b) (4) (b) (4)	03 Mar 2021 13:06:10
' answered with 'updated per query' (Site from DM).		
User entered 'No (N)' reason for change: Data Entry Error	Amy Anderson (b) (4) (b) (4)	03 Mar 2021 13:06:02
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol (related to COVID 19). Review and update entry as appropriate.	(b) (4), (b) (6)	02 Mar 2021 07:59:07
' (Site from DM).		
User entered 'Yes (Y)' reason for change: Data Entry Error	Sarah Bechnak (b) (4) (b) (4)	11 Feb 2021 15:40:46
User entered 'No (N)'	Amy Anderson (b) (4) (b) (4)	08 Feb 2021 16:14:33

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:51:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:12:24
User entered empty.	System	08 Feb 2021 16:14:33

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:51:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:12:24
User entered empty.	System	08 Feb 2021 16:14:33

US3482286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:51:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:12:24
User entered empty.	System	08 Feb 2021 16:14:33

US3482286

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:51:52

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:02:08
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 14:51:11

US3482286

Folder: SAE USA-US106-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:51:52

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:04:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:45:14
User entered 'USA-US106-2021-MRNA-1273-P301000010'	System	03 Feb 2021 21:44:59

US3482286

Folder: SAE USA-US106-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:51:52

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:04:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:45:14
User entered 'No (N)'	System	03 Feb 2021 21:44:59

US3482286

Folder: SAE USA-US106-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:51:52

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:04:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:45:14
User entered 'No (N)'	System	03 Feb 2021 21:44:59

US3482286

Folder: SAE USA-US106-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:51:52

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:04:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:45:14
User entered 'No (N)'	System	03 Feb 2021 21:44:59

US3482286

Folder: SAE USA-US106-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:51:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:04:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:45:14
User entered 'No (N)'	System	03 Feb 2021 21:44:59

US3482286

Folder: SAE USA-US106-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:51:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:04:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:45:14
User entered 'No (N)'	System	03 Feb 2021 21:44:59

US3482286

Folder: SAE USA-US106-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:51:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:04:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:45:14
User entered 'No (N)'	System	03 Feb 2021 21:44:59

US3482286

Folder: SAE USA-US106-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:51:52

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:04:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:45:14
User entered 'No (N)'	System	03 Feb 2021 21:44:59

US3482286

Folder: SAE USA-US106-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:51:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:04:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:45:14
User entered 'Easton'	System	03 Feb 2021 21:44:59

US3482286

Folder: SAE USA-US106-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:51:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:04:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:45:14
User entered 'Beshears'	System	03 Feb 2021 21:44:59

US3482286

Folder: SAE USA-US106-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:51:52

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:04:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:11:48
User entered empty.	Amy Anderson (b) (4) (b) (4)	08 Feb 2021 16:08:44

US3482286

Folder: SAE USA-US106-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:51:52

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:04:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:11:48
User entered empty.	Amy Anderson (b) (4) (b) (4)	08 Feb 2021 16:08:44

US3482286

Folder: SAE USA-US106-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:51:52

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:04:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:11:48
User entered empty.	Amy Anderson (b) (4) (b) (4)	08 Feb 2021 16:08:44

US3482286

Folder: SAE USA-US106-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:51:52

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:04:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:11:48
User entered empty.	Amy Anderson (b) (4) (b) (4)	08 Feb 2021 16:08:44

US3482286

Folder: SAE USA-US106-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:51:52

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:04:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:11:48
User entered 'US'	System	03 Feb 2021 21:45:25

US3482286

Folder: SAE USA-US106-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:51:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	04 Mar 2021 21:12:15
User entered '1'	System	03 Feb 2021 21:45:25

US3482286

Folder: SAE USA-US106-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:51:52

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:04:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:45:14
User entered 'USA-US106-2021-MRNA-1273-P301000010'	System	03 Feb 2021 21:44:59

US3482286

Folder: SAE USA-US106-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:51:52

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:04:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:45:14
User entered 'No (N)'	System	03 Feb 2021 21:44:59

US3482286

Folder: SAE USA-US106-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:51:52

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:04:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:45:14
User entered 'No (N)'	System	03 Feb 2021 21:44:59

US3482286

Folder: SAE USA-US106-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:51:52

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:04:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:45:14
User entered 'No (N)'	System	03 Feb 2021 21:44:59

US3482286

Folder: SAE USA-US106-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:51:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:04:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:45:14
User entered 'No (N)'	System	03 Feb 2021 21:44:59

US3482286

Folder: SAE USA-US106-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:51:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:04:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:45:14
User entered 'No (N)'	System	03 Feb 2021 21:44:59

US3482286

Folder: SAE USA-US106-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:51:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:04:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:45:14
User entered 'No (N)'	System	03 Feb 2021 21:44:59

US3482286

Folder: SAE USA-US106-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:51:52

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:04:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:45:14
User entered 'No (N)'	System	03 Feb 2021 21:44:59

US3482286

Folder: SAE USA-US106-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:51:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:04:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:45:14
User entered 'Easton'	System	03 Feb 2021 21:44:59

US3482286

Folder: SAE USA-US106-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:51:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:04:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:45:14
User entered 'Beshears'	System	03 Feb 2021 21:44:59

US3482286

Folder: SAE USA-US106-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:51:52

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:04:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:11:48
User entered empty.	Amy Anderson (b) (4) (b) (4)	08 Feb 2021 16:08:44

US3482286

Folder: SAE USA-US106-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:51:52

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:04:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:11:48
User entered empty.	Amy Anderson (b) (4) (b) (4)	08 Feb 2021 16:08:44

US3482286

Folder: SAE USA-US106-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:51:52

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:04:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:11:48
User entered empty.	Amy Anderson (b) (4) (b) (4)	08 Feb 2021 16:08:44

US3482286

Folder: SAE USA-US106-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:51:52

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:04:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:11:48
User entered empty.	Amy Anderson (b) (4) (b) (4)	08 Feb 2021 16:08:44

US3482286

Folder: SAE USA-US106-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:51:52

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:04:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:11:48
User entered 'US'	System	03 Feb 2021 21:45:25

US3482286

Folder: SAE USA-US106-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:51:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	04 Mar 2021 21:12:15
User entered '1'	System	03 Feb 2021 21:45:25

US3482286

Folder: SAE USA-US106-2021-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:51:52

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:04:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered '03/Feb/2021 16:45'	(b) (4) System	03 Feb 2021 21:45:25

US3482286

Folder: SAE USA-US106-2021-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:51:52

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)	21 Apr 2021 21:04:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:11:48
User entered 'I'	(b) (4), (b) (6)	03 Feb 2021 21:45:25

US3482286

Folder: SAE USA-US106-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:51:52

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:04:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:45:14
User entered 'USA-US106-2021-MRNA-1273-P301000010'	System	03 Feb 2021 21:44:59

US3482286

Folder: SAE USA-US106-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:51:52

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:04:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:45:14
User entered 'No (N)'	System	03 Feb 2021 21:44:59

US3482286

Folder: SAE USA-US106-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:51:52

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:04:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:45:14
User entered 'No (N)'	System	03 Feb 2021 21:44:59

US3482286

Folder: SAE USA-US106-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:51:52

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:04:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:45:14
User entered 'No (N)'	System	03 Feb 2021 21:44:59

US3482286

Folder: SAE USA-US106-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:51:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:04:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:45:14
User entered 'No (N)'	System	03 Feb 2021 21:44:59

US3482286

Folder: SAE USA-US106-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:51:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:04:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:45:14
User entered 'No (N)'	System	03 Feb 2021 21:44:59

US3482286

Folder: SAE USA-US106-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:51:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:04:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:45:14
User entered 'No (N)'	System	03 Feb 2021 21:44:59

US3482286

Folder: SAE USA-US106-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:51:52

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:04:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:45:14
User entered 'No (N)'	System	03 Feb 2021 21:44:59

US3482286

Folder: SAE USA-US106-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:51:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:04:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:45:14
User entered 'Easton'	System	03 Feb 2021 21:44:59

US3482286

Folder: SAE USA-US106-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:51:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:04:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:45:14
User entered 'Beshears'	System	03 Feb 2021 21:44:59

US3482286

Folder: SAE USA-US106-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:51:52

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:04:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:11:48
User entered empty.	Amy Anderson (b) (4) (b) (4)	08 Feb 2021 16:08:44

US3482286

Folder: SAE USA-US106-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:51:52

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:04:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:11:48
User entered empty.	Amy Anderson (b) (4) (b) (4)	08 Feb 2021 16:08:44

US3482286

Folder: SAE USA-US106-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:51:52

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:04:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:11:48
User entered empty.	Amy Anderson (b) (4) (b) (4)	08 Feb 2021 16:08:44

US3482286

Folder: SAE USA-US106-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:51:52

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:04:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:11:48
User entered empty.	Amy Anderson (b) (4) (b) (4)	08 Feb 2021 16:08:44

US3482286

Folder: SAE USA-US106-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:51:52

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:04:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:11:48
User entered 'US'	System	03 Feb 2021 21:45:25

US3482286

Folder: SAE USA-US106-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:51:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	04 Mar 2021 21:12:15
User entered '1'	System	03 Feb 2021 21:45:25

US3482286

Folder: SAE USA-US106-2021-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:51:52

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:04:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered '04/Mar/2021 16:12'	(b) (4) System	04 Mar 2021 21:12:15

US3482286

Folder: SAE USA-US106-2021-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:51:52

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)	21 Apr 2021 21:04:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:33:36
User entered 'I'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:15