

US3362124 (Prod: Meridian Clinical Research-(Baton Rouge, Louisiana) - Platinum - PPDS)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:36:21

All time stamps listed in this document are displayed in GMT

US3362124

Form: Participant Creation

Data signed: (b) (4) 24 Apr 2021 00:16:55

Generated On: 11 Aug 2021 22:36:21

[Participant ID](#)

US3362124

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

US3362124

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 10 Apr 2021 00:17:54

Generated On: 11 Aug 2021 22:36:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3362124

Folder: Screening

Form: Demographics

Data signed: (b) (4) 10 Apr 2021 00:17:54

Generated On: 11 Aug 2021 22:36:21

Date of Birth (MMM yyyy)	(b) (6) 2000
Age	20
Age Units	YEARS
Age (Derived)	20
Sex	Female <input type="checkbox"/> Male <input checked="" type="checkbox"/>
Ethnicity	Hispanic or Latino <input checked="" type="checkbox"/> Not Hispanic or Latino <input type="checkbox"/> Not Reported <input type="checkbox"/> Unknown <input type="checkbox"/>
Race (Check All That Apply)	
White	False
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	True
Not reported	False

US3362124

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 10 Apr 2021 00:17:54

Generated On: 11 Aug 2021 22:36:21

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

US3362124

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 10 Apr 2021 00:17:54

Generated On: 11 Aug 2021 22:36:21

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3362124

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 10 Apr 2021 00:17:54

Generated On: 11 Aug 2021 22:36:21

Were any significant conditions reported?

Yes ☒
No ☐

US3362124

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 10 Apr 2021 00:17:54

Generated On: 11 Aug 2021 22:36:21

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

US3362124

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 10 Apr 2021 00:17:54

Generated On: 11 Aug 2021 22:36:21

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	13 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	09:05 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 09:05
Height (<i>xxx.x</i>)	181 cm
Weight (<i>xxx.x</i>)	90.2 kg
BMI (<i>xxx.x</i>)	27.53274 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)	

US3362124

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 10 Apr 2021 00:17:54

Generated On: 11 Aug 2021 22:36:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 AUG 2020

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

US3362124

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 10 Apr 2021 00:17:54

Generated On: 11 Aug 2021 22:36:21

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

EXERCISES AT GYM
REGULARLY

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

US3362124

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 10 Apr 2021 00:17:54

Generated On: 11 Aug 2021 22:36:21

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

US3362124

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 14:04:28

Generated On: 11 Aug 2021 22:36:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3362124

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 20 Feb 2021 14:04:28

Generated On: 11 Aug 2021 22:36:21

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

What was the participant's randomization number? 103390

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 ☒

US3362124

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 20 Feb 2021 14:04:28

Generated On: 11 Aug 2021 22:36:21

Height	ND - Not Done
Weight	ND - Not Done

US3362124

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 20 Feb 2021 14:04:28

Generated On: 11 Aug 2021 22:36:21

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 AUG 2020
Time of assessment (00:00-23:59)	09:05 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 09:05
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3362124

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Feb 2021 14:04:28

Generated On: 11 Aug 2021 22:36:21

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 AUG 2020
Time of assessment (00:00-23:59)	10:49 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 10:49
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3362124

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 14:04:28

Generated On: 11 Aug 2021 22:36:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 AUG 2020

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

US3362124

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 20 Feb 2021 14:04:28

Generated On: 11 Aug 2021 22:36:21

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 AUG 2020

What was the treatment time? (00:00-23:59) 10:11 (24 HR)

Treatment Date and Time (derived) 13 AUG 2020 10:11

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

US3362124

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 14:04:28

Generated On: 11 Aug 2021 22:36:21

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

13 AUG 2020

Collection time (00:00-23:59)

09:27 (24 HR)

Collection date and time (derived)

13 AUG 2020 09:27

US3362124

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 14:04:28

Generated On: 11 Aug 2021 22:36:21

Collection date (dd MMM yyyy)			13 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:32	13 AUG 2020 09:32
Nasopharyngeal Swab 2	No		

US3362124

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:04:28

Generated On: 11 Aug 2021 22:36:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:36:21

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

97.8 °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 AUG 2020 10:46

PC Open Date & Time

13 AUG 2020 10:31

PC Close Date & Time

13 AUG 2020 13:01

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.0 °F

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

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

PC Time Stamp	13 AUG 2020 18:20
PC Open Date & Time	13 AUG 2020 13:56
PC Close Date & Time	14 AUG 2020 11:59

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:36:21

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

97.3 °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

14 AUG 2020 16:21

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

15 AUG 2020 21:53

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:36:21

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

16 AUG 2020 22:38

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 AUG 2020 20:59

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

18 AUG 2020 21:48

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °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

19 AUG 2020 13:45

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 10:46

PC Open Date & Time

13 AUG 2020 10:31

PC Close Date & Time

13 AUG 2020 13:01

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:36:21

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 AUG 2020 18:20

PC Open Date & Time

13 AUG 2020 13:56

PC Close Date & Time

14 AUG 2020 11:59

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:36:21

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 AUG 2020 16:21

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:36:21

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 AUG 2020 21:54

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:36:21

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 AUG 2020 22:39

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:36:21

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

17 AUG 2020 20:59

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:36:21

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 AUG 2020 21:48

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:36:21

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

19 AUG 2020 13:45

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:36:21

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 ☐

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:36:21

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

No ☐

Yes ☒

PC Time stamp	13 AUG 2020 10:47
PC Open Date & Time	13 AUG 2020 10:31
PC Close Date & Time	13 AUG 2020 13:01

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:36:21

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 ☐

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:36:21

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

No ☒

Yes ☐

PC Time stamp	13 AUG 2020 18:21
PC Open Date & Time	13 AUG 2020 13:56
PC Close Date & Time	14 AUG 2020 11:59

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:36:21

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 ☒

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:36:21

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 16:22
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:36:21

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 ☒

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:36:21

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 21:54
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:36:21

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 ☒

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:36:21

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 22:39
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:36:21

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 ☒

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:36:21

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 20:59
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:36:21

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 ☒

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:36:21

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 21:49
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:36:21

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 2410

EAB) (1725)

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:36:21

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 13:45
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3362124

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 20 AUG 2020 20:21

PC Open Date & Time 20 AUG 2020 12:00

PC Close Date & Time 21 AUG 2020 11:59

US3362124

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 21 AUG 2020 18:12

PC Open Date & Time 21 AUG 2020 12:00

PC Close Date & Time 22 AUG 2020 11:59

US3362124

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 22 AUG 2020 21:02

PC Open Date & Time 22 AUG 2020 12:00

PC Close Date & Time 23 AUG 2020 11:59

US3362124

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 23 AUG 2020 20:15

PC Open Date & Time 23 AUG 2020 12:00

PC Close Date & Time 24 AUG 2020 11:59

US3362124

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	20 AUG 2020 20:21
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3362124

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	21 AUG 2020 18:13
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3362124

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	22 AUG 2020 21:02
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3362124

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT	DAY 11
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	23 AUG 2020 20:15
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3362124

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 14:04:28

Generated On: 11 Aug 2021 22:36:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362124

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:04:28

Generated On: 11 Aug 2021 22:36:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362124

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 14:04:28

Generated On: 11 Aug 2021 22:36:21

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

IN CONVALESCENT VISITS

If Contact Not Made, please provide Comments

US3362124

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:04:28

Generated On: 11 Aug 2021 22:36:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362124

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 14:04:28

Generated On: 11 Aug 2021 22:36:21

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

PATIENT IN ILLNESS VISIT

If Contact Not Made, please provide Comments

US3362124

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:04:28

Generated On: 11 Aug 2021 22:36:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362124

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 14:04:29

Generated On: 11 Aug 2021 22:36:21

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy)

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

Folder OID VISIT2

US3362124

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:04:29

Generated On: 11 Aug 2021 22:36:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362124

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 14:04:28

Generated On: 11 Aug 2021 22:36:21

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

ILLNESS VISIT

If Contact Not Made, please provide Comments

US3362124

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:04:28

Generated On: 11 Aug 2021 22:36:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362124

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 14:04:28

Generated On: 11 Aug 2021 22:36:21

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

ILLNESS CALL

If Contact Not Made, please provide Comments

US3362124

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:04:28

Generated On: 11 Aug 2021 22:36:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362124

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 14:04:28

Generated On: 11 Aug 2021 22:36:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362124

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:04:28

Generated On: 11 Aug 2021 22:36:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362124

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 14:04:29

Generated On: 11 Aug 2021 22:36:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3362124

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 20 Feb 2021 14:04:29

Generated On: 11 Aug 2021 22:36:21

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	05 OCT 2020
Time of assessment (00:00-23:59)	09:25 (24 HR)
Vital Signs Date and Time (derived)	05 OCT 2020 09:25
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	57 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3362124

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 14:04:29

Generated On: 11 Aug 2021 22:36:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 OCT 2020

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

US3362124

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 14:04:29

Generated On: 11 Aug 2021 22:36:21

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	5 OCT 2020
Collection time (00:00-23:59)	09:30 (24 HR)
Collection date and time (derived)	5 OCT 2020 09:30

US3362124

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:04:29

Generated On: 11 Aug 2021 22:36:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	13 OCT 2020 11:08:42
Patient Cloud Open Date & Time	13 OCT 2020 00:01
Patient Cloud Close Date & Time	17 OCT 2020 23:59

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

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

Date and time of submission

Patient Cloud Open Date & Time

20 OCT 2020 00:01

Patient Cloud Close Date & Time

24 OCT 2020 23:59

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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)	True
Chills	False
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	True
Congestion	True
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	29 OCT 2020 11:20:06
Patient Cloud Open Date & Time	27 OCT 2020 00:01
Patient Cloud Close Date & Time	31 OCT 2020 23:59

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 NOV 2020 00:23:53

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT	DAY 99
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"/>

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

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

Date and time of submission

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

[Patient Cloud Close Date & Time](#)

25 NOV 2020 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

[Patient Cloud Close Date & Time](#)

02 DEC 2020 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 DEC 2020 10:52:51
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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="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"/>

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 DEC 2020 13:11:19

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 DEC 2020 23:02:55

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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 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"/>

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2021 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 JAN 2021 11:09:02
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 JAN 2021 11:03:37
Patient Cloud Open Date & Time	16 JAN 2021 00:01
Patient Cloud Close Date & Time	20 JAN 2021 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 JAN 2021 00:11:21
Patient Cloud Open Date & Time	23 JAN 2021 00:01
Patient Cloud Close Date & Time	27 JAN 2021 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 JAN 2021 18:41:43

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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	07 FEB 2021 09:56:47
Patient Cloud Open Date & Time	06 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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	13 FEB 2021 17:09:14
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 FEB 2021 00:01
Patient Cloud Close Date & Time	24 FEB 2021 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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	28 FEB 2021 23:06:09
Patient Cloud Open Date & Time	27 FEB 2021 00:01
Patient Cloud Close Date & Time	03 MAR 2021 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 MAR 2021 15:20:51

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 MAR 2021 01:23:10

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

DAY 222

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

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

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

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

[Patient Cloud Open Date & Time](#)

20 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2021 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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 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 MAR 2021 00:33:19
Patient Cloud Open Date & Time	27 MAR 2021 00:01
Patient Cloud Close Date & Time	31 MAR 2021 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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="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"/>

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

[Patient Cloud Close Date & Time](#)

07 APR 2021 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 APR 2021 19:46:04

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 APR 2021 01:12:28

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

[Patient Cloud Close Date & Time](#)

28 APR 2021 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2021 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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"/>

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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="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"/>

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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"/>

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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"/>

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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"/>

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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 <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"/>

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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"/>

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUN 2021 00:01
Patient Cloud Close Date & Time	30 JUN 2021 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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"/>

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

[Patient Cloud Open Date & Time](#)

10 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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"/>

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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"/>

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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 ☐

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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 ☐

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

14 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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="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"/>

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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"/>

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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"/>

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

DAY 432

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

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

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

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

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

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

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

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

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

[Patient Cloud Open Date & Time](#)

16 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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"/>

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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"/>

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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"/>

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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"/>

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 NOV 2021 00:01
Patient Cloud Close Date & Time	17 NOV 2021 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

DAY 467

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

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

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

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

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

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

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

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

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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 ☐

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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"/>

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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"/>

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 DEC 2021 00:01
Patient Cloud Close Date & Time	15 DEC 2021 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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"/>

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 DEC 2021 00:01
Patient Cloud Close Date & Time	22 DEC 2021 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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"/>

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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 <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"/>

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JAN 2022 00:01
Patient Cloud Close Date & Time	05 JAN 2022 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

DAY 516

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

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

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

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

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

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

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

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

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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 <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"/>

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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="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"/>

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

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02 FEB 2022 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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"/>

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

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

Date and time of submission

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09 FEB 2022 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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 ☐

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

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16 FEB 2022 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

DAY 558

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

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

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

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

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

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

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

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

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

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

Date and time of submission

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23 FEB 2022 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

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

Date and time of submission

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US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

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US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

DAY 579

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

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

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

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

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

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

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

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

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

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

Date and time of submission

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US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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"/>

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

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23 MAR 2022 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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 ☐

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

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US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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="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"/>

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

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06 APR 2022 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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"/>

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

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

Date and time of submission

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13 APR 2022 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

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Form: Safety Follow Up Diary

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 APR 2022 00:01
Patient Cloud Close Date & Time	20 APR 2022 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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"/>

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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"/>

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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"/>

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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"/>

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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"/>

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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="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"/>

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

DAY 698

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

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

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

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

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

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

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 ☐

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUL 2022 00:01
Patient Cloud Close Date & Time	13 JUL 2022 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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"/>

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2022 00:01

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20 JUL 2022 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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="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"/>

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

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

Date and time of submission

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23 JUL 2022 00:01

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27 JUL 2022 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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"/>

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

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03 AUG 2022 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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"/>

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

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10 AUG 2022 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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="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"/>

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

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

Date and time of submission

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20 AUG 2022 00:01

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24 AUG 2022 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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"/>

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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"/>

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2022 00:01

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14 SEP 2022 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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"/>

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 SEP 2022 00:01
Patient Cloud Close Date & Time	28 SEP 2022 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

[Patient Cloud Open Date & Time](#)

01 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 OCT 2022 00:01
Patient Cloud Close Date & Time	19 OCT 2022 23:59

US3362124

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:36:21

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 23:06:15

US3362124

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 06 Mar 2021 04:20:44

Generated On: 11 Aug 2021 22:36:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362124

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 06 Mar 2021 04:20:44

Generated On: 11 Aug 2021 22:36:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362124

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 00:16:57

Generated On: 11 Aug 2021 22:36:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362124

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 00:16:57

Generated On: 11 Aug 2021 22:36:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362124

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 00:16:57

Generated On: 11 Aug 2021 22:36:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362124

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 00:16:57

Generated On: 11 Aug 2021 22:36:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362124

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 00:16:57

Generated On: 11 Aug 2021 22:36:21

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362124

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 00:16:57

Generated On: 11 Aug 2021 22:36:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362124

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 24 Apr 2021 00:17:20

Generated On: 11 Aug 2021 22:36:21

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

Visit date (dd MMM yyyy)	23 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	VISIT4
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US3362124

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 24 Apr 2021 00:17:20

Generated On: 11 Aug 2021 22:36:21

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 FEB 2021
Time of assessment (00:00-23:59)	09:15 (24 HR)
Vital Signs Date and Time (derived)	23 FEB 2021 09:15
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3362124

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Apr 2021 00:17:20

Generated On: 11 Aug 2021 22:36:21

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.

US3362124

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Apr 2021 00:17:20

Generated On: 11 Aug 2021 22:36:21

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 FEB 2021

Collection time (00:00-23:59)

09:23 (24 HR)

Collection date and time (derived)

23 FEB 2021 09:23

US3362124

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 00:17:20

Generated On: 11 Aug 2021 22:36:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362124

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 00:17:20

Generated On: 11 Aug 2021 22:36:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362124

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 00:17:20

Generated On: 11 Aug 2021 22:36:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362124

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:21

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362124

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:21

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3362124

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

Date of Contact	18 SEP 2020
Time of Contact	14:47
Date and Time of Contact (derived)	18 SEP 2020 14:47
Type of Contact	<div>Clinic Visit - Scheduled <input checked="" type="radio"/></div> <div>Clinical Visit - Unscheduled <input type="radio"/></div> <div>Safety Call <input type="radio"/></div> <div>Convalescent Tele-visit <input type="radio"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes <input checked="" type="radio"/></div> <div>No <input type="radio"/></div>

US3362124

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 24 Apr 2021 00:16:57

Generated On: 11 Aug 2021 22:36:21

Symptom Day

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

US3362124

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 24 Apr 2021 00:16:57

Generated On: 11 Aug 2021 22:36:21

	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 SEP 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	37.1 C	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

293 of 2410

US3362124

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 24 Apr 2021 00:16:57

Generated On: 11 Aug 2021 22:36:21

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

294 of 2410

US3362124

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 24 Apr 2021 00:16:57

Generated On: 11 Aug 2021 22:36:21

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 ☐

US3362124

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

Date of Visit	18 SEP 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	18 SEP 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: COVID-19 Contact

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

Date of Contact	21 AUG 2020
Time of Contact	09:00
Date and Time of Contact (derived)	21 AUG 2020 09:00
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>

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

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"/>

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

	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 AUG 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	37.5 C	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

299 of 2410

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

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

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

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

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

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"/>

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	22 AUG 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	99 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

303 of 2410

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

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

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

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

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

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"/>

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	23 AUG 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	99 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

307 of 2410

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

	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"/>

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

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 ☐

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (4)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

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"/>

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (4)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	24 AUG 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
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"/>

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (4)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

	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"/>

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (4)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

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 ☐

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (5)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

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"/>

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (5)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	25 AUG 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

315 of 2410

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (5)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

	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"/>

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (5)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

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 ☐

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (6)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

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"/>

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (6)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	26 AUG 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

319 of 2410

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (6)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

	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"/>

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (6)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

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 ☐

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (7)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

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"/>

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (7)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	27 AUG 2020	
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"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

323 of 2410

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (7)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

	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"/>

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (7)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

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 ☐

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (8)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

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"/>

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (8)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	28 AUG 2020	
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"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

327 of 2410

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (8)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

	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"/>

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (8)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

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 ☐

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (9)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

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"/>

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (9)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	29 AUG 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

331 of 2410

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (9)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

	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"/>

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (9)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

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 ☐

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (10)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

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"/>

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (10)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	30 AUG 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

335 of 2410

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (10)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

	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"/>

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (10)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

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"/>

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (11)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

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"/>

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (11)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	31 AUG 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

339 of 2410

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (11)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

	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"/>

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (11)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

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 ☐

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (12)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

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"/>

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (12)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

	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	01 SEP 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

343 of 2410

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (12)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

	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"/>

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (12)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

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 ☐

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (13)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

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"/>

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (13)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

	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	02 SEP 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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"/>

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (13)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

	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"/>

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (13)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

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 ☐

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (14)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

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"/>

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (14)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	03 SEP 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

351 of 2410

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (14)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

	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"/>

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (14)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

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 ☐

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (15)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

Symptom Day

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

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (15)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

	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 SEP 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	37.1 C	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

355 of 2410

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (15)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

	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"/>

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (15)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

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 ☐

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (16)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

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"/>

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (16)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

	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 AUG 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

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

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

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

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

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (16)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

360 of 2410

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (16)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

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

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (17)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

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"/>

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (17)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

363 of 2410

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (17)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

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

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (17)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

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

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (18)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

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"/>

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (18)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

367 of 2410

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (18)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

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

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (18)

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

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

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

Date of Visit	21 AUG 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of Test	21 AUG 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	1

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

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

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

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

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

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

If Yes, provide:

Start Date _____

End Date _____

Oxygen Saturation _____

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

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

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

Start Date _____

PRODUCTION RELEASE (v12.003

EAB) (1725)

371 of 2410

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

372 of 2410

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

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

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

[Generate Next COVID-19 Assessment](#)

Yes ☒
No ☐

US3362124

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 24 Apr 2021 00:16:57

Generated On: 11 Aug 2021 22:36:21

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	23 AUG 2020
Day 5	Yes	25 AUG 2020
Day 7	Yes	27 AUG 2020
Day 9	Yes	29 AUG 2020
Day 14	Yes	03 SEP 2020
Day 21	Yes	10 SEP 2020
Day 28	No	

US3362124

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 24 Apr 2021 00:16:57

Generated On: 11 Aug 2021 22:36:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3362124

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 24 Apr 2021 00:16:57

Generated On: 11 Aug 2021 22:36:21

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 AUG 2020
Time of assessment (00:00-23:59)	09:20 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 09:20
Height (xxx.x)	181.0 cm
Weight (xxx.x)	90.2 kg
Temperature (xxx.x)	37.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3362124

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Apr 2021 00:16:57

Generated On: 11 Aug 2021 22:36:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 AUG 2020

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

US3362124

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 24 Apr 2021 00:16:57

Generated On: 11 Aug 2021 22:36:21

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

21 AUG 2020

US3362124

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3362124

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	18 SEP 2020
Time of assessment (00:00-23:59)	14:54 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 14:54
Height (xxx.x)	181 cm
Weight (xxx.x)	90.2 kg
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	98 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3362124

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Apr 2021 00:16:56

Generated On: 11 Aug 2021 22:36:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 SEP 2020

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

US3362124

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 24 Apr 2021 00:16:55

Generated On: 11 Aug 2021 22:36:21

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

18 SEP 2020

US3362124

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

Form: Visit Date

Data signed: (b) (4) 24 Apr 2021 00:16:57

Generated On: 11 Aug 2021 22:36:21

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

Visit date (dd MMM yyyy)	25 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

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

Form: Unblinding

Data signed: (b) (4) 24 Apr 2021 00:16:57

Generated On: 11 Aug 2021 22:36:21

Date of updated informed consent (<i>dd MMM yyyy</i>)	25 JAN 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>)	25 JAN 2021
Participant randomization assignment	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/>
Actual Dose 1	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input type="radio"/> Not Administered <input checked="" type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	
Continuing with mRNA-1273	1

US3362124

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 24 Apr 2021 00:16:57

Generated On: 11 Aug 2021 22:36:21

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

US3362124

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 24 Apr 2021 00:16:57

Generated On: 11 Aug 2021 22:36:21

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)	25 JAN 2021
Time of assessment (00:00-23:59)	09:05 (24 HR)
Vital Signs Date and Time (derived)	25 JAN 2021 09:05
Temperature (xxx.x)	36.4 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG

US3362124

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 24 Apr 2021 00:16:57

Generated On: 11 Aug 2021 22:36:21

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)	25 JAN 2021
Time of assessment (00:00-23:59)	10:21 (24 HR)
Vital Signs Date and Time (derived)	25 JAN 2021 10:21
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3362124

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

Form: Physical Examination

Data signed: (b) (4) 24 Apr 2021 00:16:57

Generated On: 11 Aug 2021 22:36:21

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.

US3362124

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

Form: Exposure

Data signed: (b) (4) 24 Apr 2021 00:16:57

Generated On: 11 Aug 2021 22:36:21

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) 25 JAN 2021

What was the treatment time? (00:00-23:59) 09:44 (24 HR)

Treatment Date and Time (derived) 25 JAN 2021 09:44

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

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

US3362124

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Apr 2021 00:16:57

Generated On: 11 Aug 2021 22:36:21

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

Collection date (dd MMM yyyy)	25 JAN 2021
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Collection time (00:00-23:59)	08:57 (24 HR)
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Collection date and time (derived)	25 JAN 2021 08:57
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US3362124

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 24 Apr 2021 00:16:57

Generated On: 11 Aug 2021 22:36:21

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	25 JAN 2021
Collection time (00:00 - 23:59)	08:53
Collection Date and Time (derived)	25 JAN 2021 08:53

US3362124

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

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 00:16:57

Generated On: 11 Aug 2021 22:36:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362124

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 00:17:20

Generated On: 11 Aug 2021 22:36:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362124

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 00:17:20

Generated On: 11 Aug 2021 22:36:21

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

US3362124

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 24 Apr 2021 00:16:57

Generated On: 11 Aug 2021 22:36:21

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

Visit date (dd MMM yyyy)	23 FEB 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	OLD29
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US3362124

Folder: OL-D29 (1)

Form: Vital Signs

Data signed: (b) (4) 24 Apr 2021 00:16:57

Generated On: 11 Aug 2021 22:36:21

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	23 FEB 2021
Time of assessment (<i>00:00-23:59</i>)	09:15 (24 HR)
Vital Signs Date and Time (derived)	23 FEB 2021 09:15
Temperature (<i>xxx.x</i>)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	76 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	69 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3362124

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 24 Apr 2021 00:16:57

Generated On: 11 Aug 2021 22:36:21

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 FEB 2021
Time of assessment (00:00-23:59)	09:15 (24 HR)
Vital Signs Date and Time (derived)	23 FEB 2021 09:15
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

US3362124

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 24 Apr 2021 00:16:57

Generated On: 11 Aug 2021 22:36:21

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

US3362124

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Apr 2021 00:16:57

Generated On: 11 Aug 2021 22:36:21

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.

US3362124

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 24 Apr 2021 00:16:57

Generated On: 11 Aug 2021 22:36:21

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

PATIENT RECEIVED 1ST DOSE ON 13AUG2020 DURING BLINDED PHASE, AND 2ND DOSE ON 25JAN2021 DURING OPEN-LABEL PHASE.

What was the study treatment? _____

What was the treatment date? (dd MMM yyyy) _____

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

Treatment Date and Time (derived) _____

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

What was the frequency of the study treatment dosing? _____

What was the route of administration for the study treatment? _____

US3362124

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Apr 2021 00:16:57

Generated On: 11 Aug 2021 22:36:21

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 FEB 2021

Collection time (00:00-23:59)

09:23 (24 HR)

Collection date and time (derived)

23 FEB 2021 09:23

US3362124

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 00:16:57

Generated On: 11 Aug 2021 22:36:21

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

US3362124

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 00:17:20

Generated On: 11 Aug 2021 22:36:21

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362124

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 00:17:20

Generated On: 11 Aug 2021 22:36:21

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

US3362124

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 13 Mar 2021 22:13:51

Generated On: 11 Aug 2021 22:36:21

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3362124

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 24 Apr 2021 00:16:55

Generated On: 11 Aug 2021 22:36:21

AEID	USA-US112-2020-MRNA-1273-P30 1000001
Adverse event	SYMPTOMATIC 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)	18 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	18 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

407 of 2410

US3362124

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 24 Apr 2021 00:16:55

Generated On: 11 Aug 2021 22:36:21

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3362124

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 24 Apr 2021 00:16:55

Generated On: 11 Aug 2021 22:36:21

AEID

Adverse event

JOINT ACHES IN SEVERAL
JOINTS

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☒

No ☐

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

14 AUG 2020

Start time (00:00-23:59)

00:00 (24 HR)

AE start date and time (derived)

14 AUG 2020 00:00

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

23 AUG 2020

End time (00:00-23:59)

00:00 (24 HR)

AE End Date and Time (derived)

23 AUG 2020 00:00

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

PRODUCTION RELEASE (v12.003

409 of 2410

EAB) (1725)

US3362124

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 24 Apr 2021 00:16:55

Generated On: 11 Aug 2021 22:36:21

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

US3362124

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 09 Apr 2021 00:51:39

Generated On: 11 Aug 2021 22:36:21

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

Yes ☒

No ☐

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

US3362124

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 00:51:39

Generated On: 11 Aug 2021 22:36:21

Name of Medication FLONASE

Prophylaxis Yes ☐
No ☒

Indication ALLERGIC RHINITIS

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

412 of 2410

EAB) (1725)

US3362124

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 00:51:39

Generated On: 11 Aug 2021 22:36:21

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3362124

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 00:51:39

Generated On: 11 Aug 2021 22:36:21

Name of Medication DUEXIS TOPICAL

Prophylaxis Yes ☐
No ☒

Indication SARS-COV 2 INFECTION

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

414 of 2410

EAB) (1725)

US3362124

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 00:51:39

Generated On: 11 Aug 2021 22:36:21

	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)	21 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		21 AUG 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3362124

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Apr 2021 00:51:39

Generated On: 11 Aug 2021 22:36:21

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3362124

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Data signed: (b) (4) 24 Apr 2021 00:16:57

Generated On: 11 Aug 2021 22:36:21

Visit	Screening	<input type="checkbox"/>
	Visit 1 Day 1	<input type="checkbox"/>
	Visit 2 Day 29	<input checked="" type="checkbox"/>
	Visit 3 Day 57	<input type="checkbox"/>
	Visit 4 Day 209	<input type="checkbox"/>
	Visit 5 Day 394	<input type="checkbox"/>
	Visit 6 Day 759	<input type="checkbox"/>

Case Report Form

Visit Date	True
Demographics	False
Enrollment	False
Inclusion/Exclusion Criteria Summary	False
Inclusion/Exclusion Criteria	False
Medical History Summary	False
Medical History	False
Vital Signs	False
Vital Signs - Dosing	False
Physical Examination	False
Central Laboratory - Nasopharyngeal Swab	False
Childbearing Potential	False
Pregnancy Test	False
Randomization	False
Exposure	False
Immunogenicity Assessment	False
Saliva Collection	False
COVID Diagnostic Test	False
Symptom Log	False
Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection	False
COVID-19 Severity Assessment	False
COVID-19 Contact	False
Risk of Exposure	False
Safety Call	False
Dosing Discontinuation	False

US3362124

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Data signed: (b) (4) 24 Apr 2021 00:16:57

Generated On: 11 Aug 2021 22:36:21

End of Study / Study Discontinuation	False
All	False
Date of missed or out of window visit or assessment	17 SEP 2020
Category	
Inclusion criteria not met/Exclusion criteria met	False
Study Treatment not given	True
Missed Visit	False
Missed Assessment	False
Visit performed out of window	False
Assessment performed out of window	False
Scheduled clinical visit performed as home visit	False
Other	False
Other, specify	
Description of Relationship to COVID-19	
Clinical site closed	False
Travel restrictions	False
Quarantine due to COVID-19	False
Possible exposure to COVID-19	False
Exposure to COVID-19	False
Presumption / confirmed COVID-19	True
Symptoms of COVID-19	False
Sponsor hold due to COVID-19	False
Participant decision	False

US3362124

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 24 Apr 2021 00:16:57

Generated On: 11 Aug 2021 22:36:21

Date of dosing discontinuation (dd MMM yyyy) 21 AUG 2020

Primary reason for dosing discontinuation

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

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

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 24 Apr 2021 00:16:57

Generated On: 11 Aug 2021 22:36:21

SAEID	USA-US112-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 24 Apr 2021 00:16:57

Generated On: 11 Aug 2021 22:36:21

SAEID	USA-US112-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	27/AUG/2020 13:16
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 24 Apr 2021 00:16:57

Generated On: 11 Aug 2021 22:36:21

SAEID	USA-US112-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	14/SEP/2020 17:39
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

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 24 Apr 2021 00:16:57

Generated On: 11 Aug 2021 22:36:21

SAEID	USA-US112-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	19/NOV/2020 16:37
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

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 24 Apr 2021 00:16:57

Generated On: 11 Aug 2021 22:36:21

SAEID	USA-US112-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	03/DEC/2020 19:17
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3362124 (Prod: Meridian Clinical Research-(Baton Rouge, Louisiana) - Platinum - PPDS)

US3362124

Form: Participant Creation

Generated On: 11 Aug 2021 22:36:21

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
User entered 'US3362124'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 13:54:43

US3362124

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:36:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:25:28

US3362124

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:36:21

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User entered '13 Aug 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	19 Nov 2020 22:04:12
User closed query 'Visit date is prior to the Date of informed consent. Please review and provide any needed correction.' (Site from System).	System	19 Nov 2020 22:02:59
User opened query 'Visit date is prior to the Date of informed consent. Please review and provide any needed correction.' (Site from System).	System	19 Nov 2020 22:02:02
User entered '3 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 22:02:02
User entered '13 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 13:54:44

US3362124

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:36:21

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:25:28

US3362124

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:36:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User entered 'SCRN'	System	13 Aug 2020 15:25:28

US3362124

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User entered (b) (6) 2000'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 13:54:46

US3362124

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:36:21

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User entered '20'	(b) (4), (b) (6)	13 Aug 2020 15:25:46

US3362124

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:36:21

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User entered 'YEARS'	System	13 Aug 2020 15:25:46

US3362124

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:36:21

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User entered '20'	System	13 Aug 2020 15:19:46

US3362124

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:36:21

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User entered 'Male (M)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:25:46

US3362124

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:36:21

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4), (b) (6)	13 Aug 2020 15:25:46

US3362124

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:36:21

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 15:25:46

US3362124

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:36:21

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 15:25:46

US3362124

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:36:21

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 15:25:46

US3362124

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:36:21

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 15:25:46

US3362124

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:36:21

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:25:46

US3362124

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:36:21

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 15:25:46

US3362124

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:36:21

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:25:46

US3362124

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:36:21

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User entered 'I'	(b) (4), (b) (6)	13 Aug 2020 15:25:46

US3362124

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:36:21

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 15:25:46

US3362124

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:36:21

Date of Informed Consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User closed query 'Informed Consent Date is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	(b) (4)	19 Nov 2020 22:05:08
Query 'Informed Consent Date is not within 28 days of Visit 1. Please reconcile or confirm dates.'	System	19 Nov 2020 22:05:08
answered by data change (Site from System).		
User opened query 'Informed Consent Date is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	19 Nov 2020 22:04:23
User entered '13 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 22:04:23
User closed query 'Informed Consent Date is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	19 Nov 2020 22:02:59
Query 'Informed Consent Date is not within 28 days of Visit 1. Please reconcile or confirm dates.'	System	19 Nov 2020 22:02:59
answered by data change (Site from System).		
User entered '3 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 22:02:59
User opened query 'Informed Consent Date is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	19 Nov 2020 22:01:34
User entered '13 Aug 2020'	(b) (4), (b) (6)	13 Aug 2020 15:19:46

US3362124

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User entered 'Aug 2020'	System	13 Aug 2020 15:19:46

US3362124

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User entered '2020'	System	13 Aug 2020 15:19:46

US3362124

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:36:21

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User entered 'Amendment 2 (2)'	(b) (4), (b) (6)	13 Aug 2020 15:19:46

US3362124

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:19:46

US3362124

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:19:46

US3362124

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:36:21

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 15:19:46

US3362124

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:36:21

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	13 Aug 2020 15:19:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Aug 2020 15:19:52
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 15:19:52
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 15:19:46
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 15:19:46

US3362124

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:36:21

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 13:54:44

US3362124

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:36:21

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User entered 'I'	System	13 Aug 2020 15:19:46

US3362124

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:19:29

US3362124

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:36:21

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:20:55

US3362124

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:36:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Rhinitis allergic, LLT: Allergic rhinitis - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 21:23:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 21:23:17
Data point term sent to Coder	System	13 Aug 2020 21:21:48
User entered 'allergic rhinitis'	(b) (4), (b) (6)	13 Aug 2020 21:21:13

US3362124

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User entered 'un UNK 2019'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:21:13

US3362124

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:36:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 21:21:13

US3362124

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:36:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:21:13

US3362124

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:21:13

US3362124

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:36:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 21:21:13

US3362124

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User entered 'Jan 2019'	System	13 Aug 2020 21:21:13

US3362124

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User entered '2019'	System	13 Aug 2020 21:21:13

US3362124

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User entered empty.	System	13 Aug 2020 21:21:13

US3362124

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User entered empty.	System	13 Aug 2020 21:21:13

US3362124

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:22:08

US3362124

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User closed query 'Screening Vital Signs is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	(b) (4)	19 Nov 2020 22:05:08
Query 'Screening Vital Signs is not within 28 days of Visit 1. Please reconcile or confirm dates.' answered by data change (Site from System).	System	19 Nov 2020 22:05:08
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	19 Nov 2020 22:04:40
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	19 Nov 2020 22:04:40
User opened query 'Screening Vital Signs is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	19 Nov 2020 22:04:40
User closed query 'The Assessment Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	19 Nov 2020 22:04:40
User entered '13 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 22:04:40
User opened query 'The Assessment Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	19 Nov 2020 22:04:23
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	19 Nov 2020 22:04:12
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	19 Nov 2020 22:03:19
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	19 Nov 2020 22:03:19
User closed query 'Screening Vital Signs is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	19 Nov 2020 22:03:19
Query 'Screening Vital Signs is not within 28 days of Visit 1. Please reconcile or confirm dates.' answered by data change (Site from System).	System	19 Nov 2020 22:03:19

PRODUCTION RELEASE (v12.003
EAB) (1725)

469 of 2410

US3362124

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '3 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 22:03:19
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	19 Nov 2020 22:02:02
User opened query 'Screening Vital Signs is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	19 Nov 2020 22:01:34
User entered '13 Aug 2020'	(b) (4), (b) (6)	13 Aug 2020 21:22:08

US3362124

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
Query 'Per CDM: Please confirm if time 09:05 is AM or PM. Thank you!' canceled (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 10:31:57
User opened query 'Per CDM: Please confirm if time 09:05 is AM or PM. Thank you!' (Site from DM).		25 Sep 2020 09:49:21
User entered '09:05'		13 Aug 2020 21:22:08

US3362124

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User entered '13 Aug 2020 09:05'	System	19 Nov 2020 22:04:40
User entered '3 Aug 2020 09:05'	System	19 Nov 2020 22:03:19
User entered '13 Aug 2020 09:05'	System	13 Aug 2020 21:22:08

US3362124

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User entered '181' cm	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:22:08
DataPoint set to visible.	System	13 Aug 2020 15:19:46

US3362124

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User entered '90.2' kg	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:22:08
DataPoint set to visible.	System	13 Aug 2020 15:19:46

US3362124

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
Amendment Manager: User entered '27.53274'	System	16 Sep 2020 23:54:56
User entered '27.5'	System	13 Aug 2020 21:22:08
DataPoint set to visible.	System	13 Aug 2020 15:19:46

US3362124

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User entered 'kg/m2'	System	13 Aug 2020 21:22:08
DataPoint set to visible.	System	13 Aug 2020 15:19:46

US3362124

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Sep 2020 06:35:42
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' answered with 'COMPLETED' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 12:18:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Sep 2020 12:18:36
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 09:49:56
User entered '36.9' C	(b) (4), (b) (6)	13 Aug 2020 21:22:08

US3362124

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	25 Sep 2020 12:18:36
User entered 'Oral (Oral)'	(b) (4), (b) (6)	13 Aug 2020 21:22:08

US3362124

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 21:22:08

US3362124

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Sep 2020 12:18:36
User entered '62'	(b) (4), (b) (6)	13 Aug 2020 21:22:08

US3362124

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User entered 'bpm'	System	13 Aug 2020 21:22:08

US3362124

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Sep 2020 12:18:36
User entered '17'	(b) (4), (b) (6)	13 Aug 2020 21:22:08

US3362124

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User entered 'breaths/min'	System	13 Aug 2020 21:22:08

US3362124

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Sep 2020 12:18:36
User entered '119'	(b) (4), (b) (6)	13 Aug 2020 21:22:08

US3362124

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User entered 'mmHg'	System	13 Aug 2020 21:22:08

US3362124

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Sep 2020 12:18:36
User entered '80'	(b) (4), (b) (6)	13 Aug 2020 21:22:08

US3362124

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User entered 'mmHg'	System	13 Aug 2020 21:22:08

US3362124

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32

US3362124

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32

US3362124

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:36:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:22:20

US3362124

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:36:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User closed query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	(b) (4)	19 Nov 2020 22:05:08
Query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' answered by data change (Site from System).	System	19 Nov 2020 22:05:08
User opened query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	19 Nov 2020 22:04:56
User closed query 'The physical examination date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	19 Nov 2020 22:04:56
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	19 Nov 2020 22:04:56
User entered '13 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 22:04:56
User opened query 'The physical examination date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	19 Nov 2020 22:04:23
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	19 Nov 2020 22:04:12
User closed query 'The physical examination date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	19 Nov 2020 22:02:59
User opened query 'The physical examination date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	19 Nov 2020 22:02:29
User closed query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	19 Nov 2020 22:02:29
Query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' answered by data change (Site from System).	System	19 Nov 2020 22:02:29
User entered '3 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 22:02:29

US3362124

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:36:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	19 Nov 2020 22:01:34
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	07 Sep 2020 13:10:29
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	27 Aug 2020 16:49:09
User entered '13 Aug 2020'	(b) (4), (b) (6)	13 Aug 2020 21:22:20

US3362124

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:21

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:23:00

US3362124

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:21

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:23:00

US3362124

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:21

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)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:23:00

US3362124

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:21

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)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:23:00

US3362124

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:21

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:23:00

US3362124

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:21

[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)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:23:00

US3362124

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:21

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)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:23:00

US3362124

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:21

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)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:23:00

US3362124

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:21

[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)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:23:00

US3362124

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:21

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)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:23:00

US3362124

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:21

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)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:23:00

US3362124

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:21

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 21:23:00

US3362124

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:21

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User entered 'exercises at gym regularly'	(b) (4), (b) (6)	13 Aug 2020 21:23:00

US3362124

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:21

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 21:23:00

US3362124

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:21

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:23:00

US3362124

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:21

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)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:23:00

US3362124

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:21

[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)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:23:00

US3362124

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:21

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)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 21:23:00

US3362124

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:21

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User entered 'I'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:23:00

US3362124

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:21

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 21:23:00

US3362124

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:21

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:32
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:54
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 21:23:00

US3362124

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:36:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 15:18:57

US3362124

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:36:21

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User closed query 'Visit 1 Date is not equal to the Visit 1 Treatment Date. Please reconcile or confirm dates.' (Site from System).	(b) (4)	19 Nov 2020 22:05:08
Query 'Visit 1 Date is not equal to the Visit 1 Treatment Date. Please reconcile or confirm dates.' answered by data change (Site from System).	System	19 Nov 2020 22:05:08
User closed query 'Visit date is prior to the Date of informed consent. Please review and provide any needed correction.' (Site from System).	System	19 Nov 2020 22:05:08
User entered '13 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 22:05:08
User opened query 'Visit date is prior to the Date of informed consent. Please review and provide any needed correction.' (Site from System).	System	19 Nov 2020 22:04:23
User closed query 'Visit date is prior to the Date of informed consent. Please review and provide any needed correction.' (Site from System).	System	19 Nov 2020 22:02:59
User opened query 'Visit 1 Date is not equal to the Visit 1 Treatment Date. Please reconcile or confirm dates.' (Site from System).	System	19 Nov 2020 22:01:34
User opened query 'Visit date is prior to the Date of informed consent. Please review and provide any needed correction.' (Site from System).	System	19 Nov 2020 22:01:34
User entered '3 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 22:01:34
User entered '13 Aug 2020'	(b) (4), (b) (6)	13 Aug 2020 15:18:57

US3362124

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:36:21

[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 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:18:57

US3362124

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:36:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User entered 'VISIT1'	System	13 Aug 2020 15:18:57

US3362124

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User closed query 'The Randomization Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	19 Nov 2020 22:05:08
Query 'The Randomization Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	19 Nov 2020 22:05:08
User opened query 'The Randomization Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	19 Nov 2020 22:01:34
User entered '13 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 14:39:45

US3362124

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:36:21

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 04:06:47
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:06:47
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Aug 2020 14:39:45
User entered '103390' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 14:39:45

US3362124

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:36:21

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 14:39:45

US3362124

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:36:21

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 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:19:19

US3362124

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:36:21

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 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:19:19

US3362124

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:36:21

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 15:19:19

US3362124

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:36:21

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 15:19:19

US3362124

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:36:21

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 15:19:19

US3362124

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:36:21

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 20:52:04
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:19:28
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:58:09

US3362124

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:36:21

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 20:51:52
User entered '181' cm	(b) (4), (b) (6)	13 Aug 2020 21:24:21

US3362124

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:36:21

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 20:51:52
User entered '90.2' kg	(b) (4), (b) (6)	13 Aug 2020 21:24:21

US3362124

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:36:21

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 20:51:52
User entered '181' cm	(b) (4), (b) (6)	13 Aug 2020 21:24:21

US3362124

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:36:21

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 20:51:52
User entered '90.2' kg	(b) (4), (b) (6)	13 Aug 2020 21:24:21

US3362124

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	13 Aug 2020 21:24:21

US3362124

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:24:21

US3362124

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	19 Nov 2020 22:05:08
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	19 Nov 2020 22:01:34
User entered '13 Aug 2020'	(b) (4), (b) (6)	13 Aug 2020 21:24:21

US3362124

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:21

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered '09:05'	(b) (4), (b) (6)	13 Aug 2020 21:24:21

US3362124

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User entered '13 Aug 2020 09:05'	System	13 Aug 2020 21:24:21

US3362124

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered '36.9' C	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:24:21

US3362124

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:24:21

US3362124

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:24:21

US3362124

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered '62'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:24:21

US3362124

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User entered 'bpm'	System	13 Aug 2020 21:24:21

US3362124

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered '17'	(b) (4), (b) (6)	13 Aug 2020 21:24:21

US3362124

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User entered 'breaths/min'	System	13 Aug 2020 21:24:21

US3362124

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:21

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered '119'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:24:21

US3362124

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User entered 'mmHg'	System	13 Aug 2020 21:24:21

US3362124

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:21

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered '80'	(b) (4), (b) (6)	13 Aug 2020 21:24:21

US3362124

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User entered 'mmHg'	System	13 Aug 2020 21:24:21

US3362124

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:36:21

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 20:51:52
User entered '181' cm	(b) (4), (b) (6)	13 Aug 2020 21:24:21

US3362124

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:36:21

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 20:51:52
User entered '90.2' kg	(b) (4), (b) (6)	13 Aug 2020 21:24:21

US3362124

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	13 Aug 2020 21:24:21

US3362124

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:24:21

US3362124

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	19 Nov 2020 22:05:08
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	19 Nov 2020 22:01:34
User entered '13 Aug 2020'	(b) (4), (b) (6)	13 Aug 2020 21:24:21

US3362124

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	17 Aug 2020 10:33:12
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with '30 minutes per protocol' (Site from System).	(b) (4), (b) (6)	13 Aug 2020 21:24:31
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		13 Aug 2020 21:24:21
User entered '10:49'	(b) (4), (b) (6)	13 Aug 2020 21:24:21

US3362124

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User entered '13 Aug 2020 10:49'	System	13 Aug 2020 21:24:21

US3362124

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered '36.5' C	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:24:21

US3362124

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:24:21

US3362124

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:24:21

US3362124

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered '60'	(b) (4), (b) (6)	13 Aug 2020 21:24:21

US3362124

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User entered 'bpm'	System	13 Aug 2020 21:24:21

US3362124

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered '18'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:24:21

US3362124

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User entered 'breaths/min'	System	13 Aug 2020 21:24:21

US3362124

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:21

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered '140'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:24:21

US3362124

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User entered 'mmHg'	System	13 Aug 2020 21:24:21

US3362124

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:21

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered '87'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:24:21

US3362124

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User entered 'mmHg'	System	13 Aug 2020 21:24:21

US3362124

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:36:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:24:43

US3362124

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:36:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	19 Nov 2020 22:05:08
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	19 Nov 2020 22:01:34
User entered '13 Aug 2020'	(b) (4), (b) (6)	13 Aug 2020 21:24:43

US3362124

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:36:21

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:22:05

US3362124

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:36:21

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:22:05

US3362124

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:36:21

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 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:22:05

US3362124

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:36:21

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User entered 'MRNA-1273 OR PLACEBO'	System	13 Aug 2020 15:22:05

US3362124

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:36:21

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User closed query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	19 Nov 2020 22:05:08
Query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	19 Nov 2020 22:05:08
User opened query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	19 Nov 2020 22:01:34
User entered '13 Aug 2020'	(b) (4), (b) (6)	13 Aug 2020 15:22:05

US3362124

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:36:21

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered '10:11'	(b) (4), (b) (6)	13 Aug 2020 15:22:05

US3362124

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:36:21

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User entered '13 Aug 2020 10:11'	System	13 Aug 2020 15:22:05

US3362124

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:36:21

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:22:05

US3362124

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:36:21

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User entered 'ONCE'	System	13 Aug 2020 15:22:05

US3362124

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:36:21

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User entered 'INTRAMUSCULAR'	System	13 Aug 2020 15:22:05

US3362124

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:36:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:25:01

US3362124

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:36:21

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	19 Nov 2020 22:05:08
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).	System	19 Nov 2020 22:05:08
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	19 Nov 2020 22:01:34
User entered '13 Aug 2020'	(b) (4), (b) (6)	13 Aug 2020 21:25:01

US3362124

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:36:21

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered '09:27'	(b) (4), (b) (6)	13 Aug 2020 21:25:01

US3362124

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:36:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User entered '13 Aug 2020 09:27'	System	13 Aug 2020 21:25:01

US3362124

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:36:21

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	19 Nov 2020 22:05:08
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).	System	19 Nov 2020 22:05:08
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	19 Nov 2020 22:01:34
User entered '13 Aug 2020'	(b) (4), (b) (6)	13 Aug 2020 21:25:16

US3362124

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:36:21

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	13 Aug 2020 21:25:16

US3362124

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:36:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:25:16

US3362124

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:36:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered '09:32'	(b) (4), (b) (6)	13 Aug 2020 21:25:16

US3362124

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:36:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User entered '13 Aug 2020 09:32'	System	13 Aug 2020 21:25:16

US3362124

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:36:21

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	13 Aug 2020 21:25:16

US3362124

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:36:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:25:16

US3362124

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:36:21

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:25:16

US3362124

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:36:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User entered empty.	System	13 Aug 2020 21:25:16

US3362124

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:36:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:25:20

US3362124

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:36:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User entered 'I'	System	13 Aug 2020 21:25:20

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
Data entry locked.	System	13 Aug 2020 15:22:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:36:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-13T10:45:17', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '39436509-ec66-416c-8da0-628dee95acfe' User entered 'Yes (Y)'	System	13 Aug 2020 15:46:12
	System	13 Aug 2020 15:46:12

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:36:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-13T10:45:59', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '39436509-ec66-416c-8da0-628dee95acfe' User entered '97.8'	System	13 Aug 2020 15:46:12
	System	13 Aug 2020 15:46:12

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-13T10:46:05', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '39436509-ec66-416c-8da0-628dee95acfe'	System	13 Aug 2020 15:46:12
User entered 'No (N)'	System	13 Aug 2020 15:46:12

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:36:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-13T10:46:09', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '39436509-ec66-416c-8da0-628dee95acfe' User entered '13 Aug 2020 10:46'	System	13 Aug 2020 15:46:12
	System	13 Aug 2020 15:46:12

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '13 Aug 2020 10:31'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '13 Aug 2020 13:01'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
Data entry locked.	System	13 Aug 2020 15:22:05
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:36:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-13T18:18:53', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '42d319d1-0bc4-4031-8b6a-f25bb494738c' User entered 'Yes (Y)'	System	13 Aug 2020 23:20:03
	System	13 Aug 2020 23:20:03

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:36:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-13T18:19:55', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '42d319d1-0bc4-4031-8b6a-f25bb494738c' User entered '98.0'	System	13 Aug 2020 23:20:03
	System	13 Aug 2020 23:20:03

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-13T18:19:57', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '42d319d1-0bc4-4031-8b6a-f25bb494738c' User entered 'No (N)'	System	13 Aug 2020 23:20:03
	System	13 Aug 2020 23:20:03

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:36:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-13T18:20:01', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '42d319d1-0bc4-4031-8b6a-f25bb494738c' User entered '13 Aug 2020 18:20'	System	13 Aug 2020 23:20:03
	System	13 Aug 2020 23:20:03

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '13 Aug 2020 13:56'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
Data entry locked.	System	13 Aug 2020 15:22:05
User entered 'Day 2'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:36:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-14T16:20:54', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'b546d048-b6ed-4676-8891-f073a906064e' User entered 'Yes (Y)'	System	14 Aug 2020 21:21:37
	System	14 Aug 2020 21:21:37

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:36:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-14T16:21:20', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'b546d048-b6ed-4676-8891-f073a906064e' User entered '97.3'	System	14 Aug 2020 21:21:37
	System	14 Aug 2020 21:21:37

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-14T16:21:22', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'b546d048-b6ed-4676-8891-f073a906064e' User entered 'No (N)'	System	14 Aug 2020 21:21:37
	System	14 Aug 2020 21:21:37

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:36:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-14T16:21:33', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'b546d048-b6ed-4676-8891-f073a906064e' User entered '14 Aug 2020 16:21'	System	14 Aug 2020 21:21:37
	System	14 Aug 2020 21:21:37

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
Data entry locked.	System	13 Aug 2020 15:22:05
User entered 'Day 3'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:36:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-15T21:53:48', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'aaa8022a-831c-4497-832c-ffa3cdb42e53' User entered 'Yes (Y)'	System	16 Aug 2020 02:53:57
	System	16 Aug 2020 02:53:57

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:36:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-15T21:53:51', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'aaa8022a-831c-4497-832c-ffa3cdb42e53' User entered '98.3'	System	16 Aug 2020 02:53:57
	System	16 Aug 2020 02:53:57

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-15T21:53:53', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'aaa8022a-831c-4497-832c-ffa3cdb42e53'	System	16 Aug 2020 02:53:57
User entered 'No (N)'	System	16 Aug 2020 02:53:57

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:36:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-15T21:53:55', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'aaa8022a-831c-4497-832c-ffa3cdb42e53'	System	16 Aug 2020 02:53:57
User entered '15 Aug 2020 21:53'	System	16 Aug 2020 02:53:57

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
Data entry locked.	System	13 Aug 2020 15:22:05
User entered 'Day 4'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:36:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-16T22:38:46', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'c6587a0d-8ad4-4c84-b8eb-8e6af1a77479' User entered 'Yes (Y)'	System	17 Aug 2020 03:39:01
	System	17 Aug 2020 03:39:01

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:36:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-16T22:38:52', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'c6587a0d-8ad4-4c84-b8eb-8e6af1a77479' User entered '97.6'	System	17 Aug 2020 03:39:01
	System	17 Aug 2020 03:39:01

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-16T22:38:54', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'c6587a0d-8ad4-4c84-b8eb-8e6af1a77479'	System	17 Aug 2020 03:39:01
User entered 'No (N)'	System	17 Aug 2020 03:39:01

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:36:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-16T22:38:59', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'c6587a0d-8ad4-4c84-b8eb-8e6af1a77479' User entered '16 Aug 2020 22:38'	System	17 Aug 2020 03:39:01
	System	17 Aug 2020 03:39:01

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
Data entry locked.	System	13 Aug 2020 15:22:05
User entered 'Day 5'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:36:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-17T20:59:01', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'e41be258-9bde-4284-bac8-3d72ac335e2e' User entered 'Yes (Y)'	System	18 Aug 2020 01:59:14
	System	18 Aug 2020 01:59:14

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:36:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-17T20:59:04', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'e41be258-9bde-4284-bac8-3d72ac335e2e' User entered '98.0'	System	18 Aug 2020 01:59:14
	System	18 Aug 2020 01:59:14

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-17T20:59:07', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'e41be258-9bde-4284-bac8-3d72ac335e2e'	System	18 Aug 2020 01:59:14
User entered 'No (N)'	System	18 Aug 2020 01:59:14

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:36:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-17T20:59:09', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'e41be258-9bde-4284-bac8-3d72ac335e2e' User entered '17 Aug 2020 20:59'	System	18 Aug 2020 01:59:14
	System	18 Aug 2020 01:59:14

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
Data entry locked.	System	13 Aug 2020 15:22:05
User entered 'Day 6'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:36:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-18T21:48:23', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'c1435b73-e806-489d-b094-2258ebf8f916'	System	19 Aug 2020 02:48:38
User entered 'Yes (Y)'	System	19 Aug 2020 02:48:38

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:36:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-18T21:48:29', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'c1435b73-e806-489d-b094-2258ebf8f916' User entered '98.3'	System	19 Aug 2020 02:48:38
	System	19 Aug 2020 02:48:38

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-18T21:48:32', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'c1435b73-e806-489d-b094-2258ebf8f916'	System	19 Aug 2020 02:48:38
User entered 'No (N)'	System	19 Aug 2020 02:48:38

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:36:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-18T21:48:36', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'c1435b73-e806-489d-b094-2258ebf8f916'	System	19 Aug 2020 02:48:38
User entered '18 Aug 2020 21:48'	System	19 Aug 2020 02:48:38

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
Data entry locked.	System	13 Aug 2020 15:22:05
User entered 'Day 7'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:36:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-19T13:44:53', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '063ed5d4-909d-4a43-a49c-36ce66942557' User entered 'Yes (Y)'	System	19 Aug 2020 18:46:11
	System	19 Aug 2020 18:46:11

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:36:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-19T13:44:57', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '063ed5d4-909d-4a43-a49c-36ce66942557' User entered '98.8'	System	19 Aug 2020 18:46:11
	System	19 Aug 2020 18:46:11

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-19T13:45:00', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '063ed5d4-909d-4a43-a49c-36ce66942557'	System	19 Aug 2020 18:46:11
User entered 'No (N)'	System	19 Aug 2020 18:46:11

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:36:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-19T13:45:02', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '063ed5d4-909d-4a43-a49c-36ce66942557'	System	19 Aug 2020 18:46:11
User entered '19 Aug 2020 13:45'	System	19 Aug 2020 18:46:11

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
Data entry locked.	System	13 Aug 2020 15:22:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:36:21

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 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-13T10:46:22', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'f9963d46-715f-42f8-aeb2-3a3be052cf59'	System	13 Aug 2020 15:46:56
User entered 'None (1)'	System	13 Aug 2020 15:46:56

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:36:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-13T10:46:37', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'f9963d46-715f-42f8-aeb2-3a3be052cf59'	System	13 Aug 2020 15:46:56
User entered 'No (N)'	System	13 Aug 2020 15:46:56

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-13T10:46:42', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'f9963d46-715f-42f8-aeb2-3a3be052cf59'	System	13 Aug 2020 15:46:56
User entered 'No (N)'	System	13 Aug 2020 15:46:56

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:36:21

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 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-13T10:46:51', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'f9963d46-715f-42f8-aeb2-3a3be052cf59'	System	13 Aug 2020 15:46:56
User entered 'None (1)'	System	13 Aug 2020 15:46:56

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:36:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-13T10:46:53', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'f9963d46-715f-42f8-aeb2-3a3be052cf59' User entered '13 Aug 2020 10:46'	System	13 Aug 2020 15:46:56
	System	13 Aug 2020 15:46:56

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '13 Aug 2020 10:31'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '13 Aug 2020 13:01'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
Data entry locked.	System	13 Aug 2020 15:22:05
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:36:21

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 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-13T18:20:07', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '646e41cc-c8df-4e60-a93e-d287f5f5f29f' User entered 'Does not interfere with activity (2)'	System	13 Aug 2020 23:20:39
	System	13 Aug 2020 23:20:39

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:36:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-13T18:20:17', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '646e41cc-c8df-4e60-a93e-d287f5f5f29f' User entered 'No (N)'	System	13 Aug 2020 23:20:39
	System	13 Aug 2020 23:20:39

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-13T18:20:27', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '646e41cc-c8df-4e60-a93e-d287f5f5f29f' User entered 'No (N)'	System	13 Aug 2020 23:20:39
	System	13 Aug 2020 23:20:39

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:36:21

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 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-13T18:20:34', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '646e41cc-c8df-4e60-a93e-d287f5f5f29f' User entered 'None (1)'	System	13 Aug 2020 23:20:39
	System	13 Aug 2020 23:20:39

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:36:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-13T18:20:36', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '646e41cc-c8df-4e60-a93e-d287f5f5f29f' User entered '13 Aug 2020 18:20'	System	13 Aug 2020 23:20:39
	System	13 Aug 2020 23:20:39

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '13 Aug 2020 13:56'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
Data entry locked.	System	13 Aug 2020 15:22:05
User entered 'Day 2'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:36:21

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 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-14T16:21:38', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '6eb8e7ab-70d4-485c-b390-f43710cfe759'	System	14 Aug 2020 21:21:55
User entered 'Does not interfere with activity (2)'	System	14 Aug 2020 21:21:55

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:36:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-14T16:21:40', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '6eb8e7ab-70d4-485c-b390-f43710cfe759'	System	14 Aug 2020 21:21:55
User entered 'No (N)'	System	14 Aug 2020 21:21:55

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-14T16:21:43', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '6eb8e7ab-70d4-485c-b390-f43710cfe759' User entered 'No (N)'	System	14 Aug 2020 21:21:55
	System	14 Aug 2020 21:21:55

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:36:21

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 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-14T16:21:47', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '6eb8e7ab-70d4-485c-b390-f43710cfe759'	System	14 Aug 2020 21:21:55
User entered 'None (1)'	System	14 Aug 2020 21:21:55

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:36:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-14T16:21:49', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '6eb8e7ab-70d4-485c-b390-f43710cfe759' User entered '14 Aug 2020 16:21'	System	14 Aug 2020 21:21:55
	System	14 Aug 2020 21:21:55

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
Data entry locked.	System	13 Aug 2020 15:22:05
User entered 'Day 3'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:36:21

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 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-15T21:53:59', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'a96dd55b-bcfb-449f-a4b4-4073cd1bfbf5'	System	16 Aug 2020 02:54:10
User entered 'Does not interfere with activity (2)'	System	16 Aug 2020 02:54:10

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:36:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-15T21:54:01', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'a96dd55b-bcfb-449f-a4b4-4073cd1bfbf5'	System	16 Aug 2020 02:54:10
User entered 'No (N)'	System	16 Aug 2020 02:54:10

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-15T21:54:03', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'a96dd55b-bcfb-449f-a4b4-4073cd1bfbf5'	System	16 Aug 2020 02:54:10
User entered 'No (N)'	System	16 Aug 2020 02:54:10

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:36:21

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 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-15T21:54:05', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'a96dd55b-bcfb-449f-a4b4-4073cd1bfbf5'	System	16 Aug 2020 02:54:10
User entered 'None (1)'	System	16 Aug 2020 02:54:10

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:36:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-15T21:54:07', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'a96dd55b-bcfb-449f-a4b4-4073cd1bfbf5'	System	16 Aug 2020 02:54:10
User entered '15 Aug 2020 21:54'	System	16 Aug 2020 02:54:10

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
Data entry locked.	System	13 Aug 2020 15:22:05
User entered 'Day 4'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:36:21

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 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-16T22:39:03', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'b45cd108-eeee-4adb-b3ae-ac7cb584878f' User entered 'None (1)'	System	17 Aug 2020 03:39:15
	System	17 Aug 2020 03:39:15

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:36:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-16T22:39:05', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'b45cd108-eeee-4adb-b3ae-ac7cb584878f' User entered 'No (N)'	System	17 Aug 2020 03:39:15
	System	17 Aug 2020 03:39:15

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-16T22:39:07', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'b45cd108-eeee-4adb-b3ae-ac7cb584878f' User entered 'No (N)'	System	17 Aug 2020 03:39:15
	System	17 Aug 2020 03:39:15

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:36:21

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 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-16T22:39:09', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'b45cd108-eeee-4adb-b3ae-ac7cb584878f' User entered 'None (1)'	System	17 Aug 2020 03:39:15
	System	17 Aug 2020 03:39:15

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:36:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-16T22:39:13', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'b45cd108-eeee-4adb-b3ae-ac7cb584878f' User entered '16 Aug 2020 22:39'	System	17 Aug 2020 03:39:15
	System	17 Aug 2020 03:39:15

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
Data entry locked.	System	13 Aug 2020 15:22:05
User entered 'Day 5'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:36:21

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 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-17T20:59:12', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '343035eb-be91-400c-a1c9-c9bc5e52fc2d' User entered 'None (1)'	System	18 Aug 2020 01:59:23
	System	18 Aug 2020 01:59:23

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:36:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-17T20:59:14', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '343035eb-be91-400c-a1c9-c9bc5e52fc2d' User entered 'No (N)'	System	18 Aug 2020 01:59:23
	System	18 Aug 2020 01:59:23

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-17T20:59:16', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '343035eb-be91-400c-a1c9-c9bc5e52fc2d' User entered 'No (N)'	System	18 Aug 2020 01:59:23
	System	18 Aug 2020 01:59:23

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:36:21

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 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-17T20:59:18', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '343035eb-be91-400c-a1c9-c9bc5e52fc2d' User entered 'None (1)'	System	18 Aug 2020 01:59:23
	System	18 Aug 2020 01:59:23

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:36:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-17T20:59:20', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '343035eb-be91-400c-a1c9-c9bc5e52fc2d' User entered '17 Aug 2020 20:59'	System	18 Aug 2020 01:59:23
	System	18 Aug 2020 01:59:23

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
Data entry locked.	System	13 Aug 2020 15:22:05
User entered 'Day 6'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:36:21

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 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-18T21:48:39', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'c393cae1-5726-42a4-b0b3-99cd40ebd67a' User entered 'None (1)'	System	19 Aug 2020 02:48:51
	System	19 Aug 2020 02:48:51

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:36:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-18T21:48:41', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'c393cae1-5726-42a4-b0b3-99cd40ebd67a' User entered 'No (N)'	System	19 Aug 2020 02:48:51
	System	19 Aug 2020 02:48:51

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-18T21:48:43', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'c393cae1-5726-42a4-b0b3-99cd40ebd67a' User entered 'No (N)'	System	19 Aug 2020 02:48:51
	System	19 Aug 2020 02:48:51

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:36:21

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 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-18T21:48:45', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'c393cae1-5726-42a4-b0b3-99cd40ebd67a' User entered 'None (1)'	System	19 Aug 2020 02:48:51
	System	19 Aug 2020 02:48:51

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:36:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-18T21:48:47', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'c393cae1-5726-42a4-b0b3-99cd40ebd67a' User entered '18 Aug 2020 21:48'	System	19 Aug 2020 02:48:51
	System	19 Aug 2020 02:48:51

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
Data entry locked.	System	13 Aug 2020 15:22:05
User entered 'Day 7'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:36:21

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 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-19T13:45:06', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '38d5a599-de17-40ca-afd1-3ebe1c4900bb' User entered 'None (1)'	System	21 Aug 2020 01:20:06
	System	21 Aug 2020 01:20:06

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:36:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-19T13:45:08', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '38d5a599-de17-40ca-afd1-3ebe1c4900bb' User entered 'No (N)'	System	21 Aug 2020 01:20:06
	System	21 Aug 2020 01:20:06

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-19T13:45:10', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '38d5a599-de17-40ca-afd1-3ebe1c4900bb' User entered 'No (N)'	System	21 Aug 2020 01:20:06
	System	21 Aug 2020 01:20:06

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:36:21

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 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-19T13:45:12', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '38d5a599-de17-40ca-afd1-3ebe1c4900bb'	System	21 Aug 2020 01:20:06
User entered 'None (1)'	System	21 Aug 2020 01:20:06

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:36:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-19T13:45:13', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '38d5a599-de17-40ca-afd1-3ebe1c4900bb' User entered '19 Aug 2020 13:45'	System	21 Aug 2020 01:20:06
	System	21 Aug 2020 01:20:06

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
Data entry locked.	System	13 Aug 2020 15:22:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:36:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-13T10:47:02', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '98f33e9c-e2e1-4a49-875e-5b8410029948' User entered 'None (0)'	System	13 Aug 2020 15:47:28
	System	13 Aug 2020 15:47:28

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:36:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-13T10:47:06', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '98f33e9c-e2e1-4a49-875e-5b8410029948' User entered 'None (0)'	System	13 Aug 2020 15:47:28
	System	13 Aug 2020 15:47:28

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:36:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-13T10:47:09', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '98f33e9c-e2e1-4a49-875e-5b8410029948' User entered 'None (0)'	System	13 Aug 2020 15:47:28
	System	13 Aug 2020 15:47:28

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:36:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-13T10:47:13', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '98f33e9c-e2e1-4a49-875e-5b8410029948' User entered 'None (0)'	System	13 Aug 2020 15:47:28
	System	13 Aug 2020 15:47:28

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:36:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-13T10:47:15', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '98f33e9c-e2e1-4a49-875e-5b8410029948' User entered 'None (0)'	System	13 Aug 2020 15:47:28
	System	13 Aug 2020 15:47:28

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:36:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-13T10:47:18', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '98f33e9c-e2e1-4a49-875e-5b8410029948' User entered 'None (0)'	System	13 Aug 2020 15:47:28
	System	13 Aug 2020 15:47:28

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:36:21

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 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-13T10:47:25', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '98f33e9c-e2e1-4a49-875e-5b8410029948' User entered 'Yes (Y)'	System	13 Aug 2020 15:47:28
	System	13 Aug 2020 15:47:28

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:36:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-13T10:47:27', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '98f33e9c-e2e1-4a49-875e-5b8410029948' User entered '13 Aug 2020 10:47'	System	13 Aug 2020 15:47:28
	System	13 Aug 2020 15:47:28

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '13 Aug 2020 10:31'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '13 Aug 2020 13:01'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
Data entry locked.	System	13 Aug 2020 15:22:05
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:36:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-13T18:20:41', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'b28f8586-bec8-44b0-be31-de81959fe546' User entered 'None (0)'	System	13 Aug 2020 23:21:02
	System	13 Aug 2020 23:21:02

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:36:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-13T18:20:45', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'b28f8586-bec8-44b0-be31-de81959fe546' User entered 'None (0)'	System	13 Aug 2020 23:21:02
	System	13 Aug 2020 23:21:02

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:36:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-13T18:20:48', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'b28f8586-bec8-44b0-be31-de81959fe546' User entered 'None (0)'	System	13 Aug 2020 23:21:02
	System	13 Aug 2020 23:21:02

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:36:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-13T18:20:50', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'b28f8586-bec8-44b0-be31-de81959fe546' User entered 'None (0)'	System	13 Aug 2020 23:21:02
	System	13 Aug 2020 23:21:02

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:36:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-13T18:20:52', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'b28f8586-bec8-44b0-be31-de81959fe546' User entered 'None (0)'	System	13 Aug 2020 23:21:02
	System	13 Aug 2020 23:21:02

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:36:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-13T18:20:54', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'b28f8586-bec8-44b0-be31-de81959fe546' User entered 'None (0)'	System	13 Aug 2020 23:21:02
	System	13 Aug 2020 23:21:02

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:36:21

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 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-13T18:20:58', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'b28f8586-bec8-44b0-be31-de81959fe546'	System	13 Aug 2020 23:21:02
User entered 'No (N)'	System	13 Aug 2020 23:21:02

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:36:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-13T18:21:00', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'b28f8586-bec8-44b0-be31-de81959fe546'	System	13 Aug 2020 23:21:02
User entered '13 Aug 2020 18:21'	System	13 Aug 2020 23:21:02

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '13 Aug 2020 13:56'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
Data entry locked.	System	13 Aug 2020 15:22:05
User entered 'Day 2'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:36:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-14T16:21:55', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '8f0c8e85-750b-4832-93e2-6af9ba411510' User entered 'None (0)'	System	14 Aug 2020 21:22:20
	System	14 Aug 2020 21:22:20

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:36:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-14T16:21:59', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '8f0c8e85-750b-4832-93e2-6af9ba411510'	System	14 Aug 2020 21:22:20
User entered 'No interference with activity (1)'	System	14 Aug 2020 21:22:20

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:36:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-14T16:22:01', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '8f0c8e85-750b-4832-93e2-6af9ba411510'	System	14 Aug 2020 21:22:20
User entered 'No interference with activity (1)'	System	14 Aug 2020 21:22:20

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:36:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-14T16:22:07', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '8f0c8e85-750b-4832-93e2-6af9ba411510'	System	14 Aug 2020 21:22:20
User entered 'No interference with activity (1)'	System	14 Aug 2020 21:22:20

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:36:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-14T16:22:09', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '8f0c8e85-750b-4832-93e2-6af9ba411510' User entered 'None (0)'	System	14 Aug 2020 21:22:20
	System	14 Aug 2020 21:22:20

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:36:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-14T16:22:10', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '8f0c8e85-750b-4832-93e2-6af9ba411510'	System	14 Aug 2020 21:22:20
User entered 'None (0)'	System	14 Aug 2020 21:22:20

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:36:21

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 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-14T16:22:14', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '8f0c8e85-750b-4832-93e2-6af9ba411510'	System	14 Aug 2020 21:22:20
User entered 'No (N)'	System	14 Aug 2020 21:22:20

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:36:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-14T16:22:15', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '8f0c8e85-750b-4832-93e2-6af9ba411510'	System	14 Aug 2020 21:22:20
User entered '14 Aug 2020 16:22'	System	14 Aug 2020 21:22:20

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
Data entry locked.	System	13 Aug 2020 15:22:05
User entered 'Day 3'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:36:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-15T21:54:11', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'ac7ed1a6-8e7c-404f-8a59-b7e25ff95b0e' User entered 'None (0)'	System	16 Aug 2020 02:54:26
	System	16 Aug 2020 02:54:26

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:36:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-15T21:54:12', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'ac7ed1a6-8e7c-404f-8a59-b7e25ff95b0e' User entered 'None (0)'	System	16 Aug 2020 02:54:26
	System	16 Aug 2020 02:54:26

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:36:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-15T21:54:14', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'ac7ed1a6-8e7c-404f-8a59-b7e25ff95b0e' User entered 'None (0)'	System	16 Aug 2020 02:54:26
	System	16 Aug 2020 02:54:26

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:36:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-15T21:54:16', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'ac7ed1a6-8e7c-404f-8a59-b7e25ff95b0e' User entered 'None (0)'	System	16 Aug 2020 02:54:26
	System	16 Aug 2020 02:54:26

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:36:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-15T21:54:17', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'ac7ed1a6-8e7c-404f-8a59-b7e25ff95b0e' User entered 'None (0)'	System	16 Aug 2020 02:54:26
	System	16 Aug 2020 02:54:26

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:36:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-15T21:54:19', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'ac7ed1a6-8e7c-404f-8a59-b7e25ff95b0e' User entered 'None (0)'	System	16 Aug 2020 02:54:26
	System	16 Aug 2020 02:54:26

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:36:21

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 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-15T21:54:22', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'ac7ed1a6-8e7c-404f-8a59-b7e25ff95b0e'	System	16 Aug 2020 02:54:26
User entered 'No (N)'	System	16 Aug 2020 02:54:26

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:36:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-15T21:54:23', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'ac7ed1a6-8e7c-404f-8a59-b7e25ff95b0e'	System	16 Aug 2020 02:54:26
User entered '15 Aug 2020 21:54'	System	16 Aug 2020 02:54:26

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
Data entry locked.	System	13 Aug 2020 15:22:05
User entered 'Day 4'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:36:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-16T22:39:17', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'c0e7d2b9-c820-4da9-af2e-ee159c8ab411' User entered 'None (0)'	System	17 Aug 2020 03:39:29
	System	17 Aug 2020 03:39:29

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:36:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-16T22:39:19', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'c0e7d2b9-c820-4da9-af2e-ee159c8ab411' User entered 'None (0)'	System	17 Aug 2020 03:39:29
	System	17 Aug 2020 03:39:29

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:36:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-16T22:39:20', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'c0e7d2b9-c820-4da9-af2e-ee159c8ab411' User entered 'None (0)'	System	17 Aug 2020 03:39:29
	System	17 Aug 2020 03:39:29

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:36:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-16T22:39:22', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'c0e7d2b9-c820-4da9-af2e-ee159c8ab411' User entered 'None (0)'	System	17 Aug 2020 03:39:29
	System	17 Aug 2020 03:39:29

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:36:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-16T22:39:23', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'c0e7d2b9-c820-4da9-af2e-ee159c8ab411' User entered 'None (0)'	System	17 Aug 2020 03:39:29
	System	17 Aug 2020 03:39:29

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:36:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-16T22:39:25', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'c0e7d2b9-c820-4da9-af2e-ee159c8ab411' User entered 'None (0)'	System	17 Aug 2020 03:39:29
	System	17 Aug 2020 03:39:29

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:36:21

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 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-16T22:39:26', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'c0e7d2b9-c820-4da9-af2e-ee159c8ab411' User entered 'No (N)'	System	17 Aug 2020 03:39:29
	System	17 Aug 2020 03:39:29

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:36:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-16T22:39:28', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'c0e7d2b9-c820-4da9-af2e-ee159c8ab411' User entered '16 Aug 2020 22:39'	System	17 Aug 2020 03:39:29
	System	17 Aug 2020 03:39:29

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
Data entry locked.	System	13 Aug 2020 15:22:05
User entered 'Day 5'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:36:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-17T20:59:24', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'e6ca4250-ba69-4065-a804-9f032808fc38' User entered 'None (0)'	System	18 Aug 2020 01:59:44
	System	18 Aug 2020 01:59:44

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:36:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-17T20:59:26', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'e6ca4250-ba69-4065-a804-9f032808fc38' User entered 'None (0)'	System	18 Aug 2020 01:59:44
	System	18 Aug 2020 01:59:44

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:36:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-17T20:59:28', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'e6ca4250-ba69-4065-a804-9f032808fc38' User entered 'None (0)'	System	18 Aug 2020 01:59:44
	System	18 Aug 2020 01:59:44

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:36:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-17T20:59:31', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'e6ca4250-ba69-4065-a804-9f032808fc38' User entered 'None (0)'	System	18 Aug 2020 01:59:44
	System	18 Aug 2020 01:59:44

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:36:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-17T20:59:33', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'e6ca4250-ba69-4065-a804-9f032808fc38' User entered 'None (0)'	System	18 Aug 2020 01:59:44
	System	18 Aug 2020 01:59:44

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:36:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-17T20:59:35', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'e6ca4250-ba69-4065-a804-9f032808fc38' User entered 'None (0)'	System	18 Aug 2020 01:59:44
	System	18 Aug 2020 01:59:44

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:36:21

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 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-17T20:59:37', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'e6ca4250-ba69-4065-a804-9f032808fc38' User entered 'No (N)'	System	18 Aug 2020 01:59:44
	System	18 Aug 2020 01:59:44

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:36:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-17T20:59:42', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'e6ca4250-ba69-4065-a804-9f032808fc38' User entered '17 Aug 2020 20:59'	System	18 Aug 2020 01:59:44
	System	18 Aug 2020 01:59:44

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
Data entry locked.	System	13 Aug 2020 15:22:05
User entered 'Day 6'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:36:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-18T21:48:51', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'f633d9b1-2761-465c-9a72-75465dd4f149' User entered 'None (0)'	System	19 Aug 2020 02:49:06
	System	19 Aug 2020 02:49:06

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:36:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-18T21:48:53', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'f633d9b1-2761-465c-9a72-75465dd4f149'	System	19 Aug 2020 02:49:06
User entered 'No interference with activity (1)'	System	19 Aug 2020 02:49:06

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:36:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-18T21:48:54', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'f633d9b1-2761-465c-9a72-75465dd4f149'	System	19 Aug 2020 02:49:06
User entered 'No interference with activity (1)'	System	19 Aug 2020 02:49:06

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:36:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-18T21:48:56', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'f633d9b1-2761-465c-9a72-75465dd4f149'	System	19 Aug 2020 02:49:06
User entered 'No interference with activity (1)'	System	19 Aug 2020 02:49:06

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:36:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-18T21:48:58', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'f633d9b1-2761-465c-9a72-75465dd4f149' User entered 'None (0)'	System	19 Aug 2020 02:49:06
	System	19 Aug 2020 02:49:06

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:36:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-18T21:48:59', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'f633d9b1-2761-465c-9a72-75465dd4f149' User entered 'None (0)'	System	19 Aug 2020 02:49:06
	System	19 Aug 2020 02:49:06

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:36:21

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 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-18T21:49:02', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'f633d9b1-2761-465c-9a72-75465dd4f149'	System	19 Aug 2020 02:49:06
User entered 'No (N)'	System	19 Aug 2020 02:49:06

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:36:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-18T21:49:04', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'f633d9b1-2761-465c-9a72-75465dd4f149'	System	19 Aug 2020 02:49:06
User entered '18 Aug 2020 21:49'	System	19 Aug 2020 02:49:06

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
Data entry locked.	System	13 Aug 2020 15:22:05
User entered 'Day 7'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:36:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-19T13:45:16', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '6dfdab5b-3e4d-4ff3-9f8d-152fd827cceb' User entered 'None (0)'	System	21 Aug 2020 01:20:06
	System	21 Aug 2020 01:20:06

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:36:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-19T13:45:18', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '6dfdab5b-3e4d-4ff3-9f8d-152fd827cceb' User entered 'None (0)'	System	21 Aug 2020 01:20:06
	System	21 Aug 2020 01:20:06

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:36:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-19T13:45:23', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '6dfdab5b-3e4d-4ff3-9f8d-152fd827cceb' User entered 'None (0)'	System	21 Aug 2020 01:20:06
	System	21 Aug 2020 01:20:06

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:36:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-19T13:45:25', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '6dfdab5b-3e4d-4ff3-9f8d-152fd827cceb'	System	21 Aug 2020 01:20:06
User entered 'No interference with activity (1)'	System	21 Aug 2020 01:20:06

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:36:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-19T13:45:27', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '6dfdab5b-3e4d-4ff3-9f8d-152fd827cceb' User entered 'None (0)'	System	21 Aug 2020 01:20:06
	System	21 Aug 2020 01:20:06

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:36:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-19T13:45:29', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '6dfdab5b-3e4d-4ff3-9f8d-152fd827cceb' User entered 'None (0)'	System	21 Aug 2020 01:20:06
	System	21 Aug 2020 01:20:06

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:36:21

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 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-19T13:45:31', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '6dfdab5b-3e4d-4ff3-9f8d-152fd827cceb' User entered 'No (N)'	System	21 Aug 2020 01:20:06
	System	21 Aug 2020 01:20:06

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:36:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-19T13:45:33', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '6dfdab5b-3e4d-4ff3-9f8d-152fd827cceb' User entered '19 Aug 2020 13:45'	System	21 Aug 2020 01:20:06
	System	21 Aug 2020 01:20:06

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 15:22:05

US3362124

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
Data entry locked.	System	19 Aug 2020 02:49:06
User entered 'Day 8'	System	19 Aug 2020 02:49:06

US3362124

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 11 Aug 2021 22:36:21

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-20T20:21:06', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'e838e722-6eb1-4fb4-a71b-50da825bc703'	System	21 Aug 2020 01:21:12
User entered 'No interference with activity (1)'	System	21 Aug 2020 01:21:12

US3362124

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 11 Aug 2021 22:36:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-20T20:21:07', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'e838e722-6eb1-4fb4-a71b-50da825bc703'	System	21 Aug 2020 01:21:12
User entered '20 Aug 2020 20:21'	System	21 Aug 2020 01:21:12

US3362124

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 11 Aug 2021 22:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 02:49:06

US3362124

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 11 Aug 2021 22:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 02:49:06

US3362124

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
Data entry locked.	System	21 Aug 2020 01:20:06
User entered 'Day 9'	System	21 Aug 2020 01:20:06

US3362124

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 11 Aug 2021 22:36:21

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-21T18:12:55', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '6c98af43-807a-464b-9d96-101f6de03f9b'	System	21 Aug 2020 23:13:02
User entered 'No interference with activity (1)'	System	21 Aug 2020 23:13:02

US3362124

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 11 Aug 2021 22:36:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-21T18:12:57', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '6c98af43-807a-464b-9d96-101f6de03f9b' User entered '21 Aug 2020 18:12'	System	21 Aug 2020 23:13:02
	System	21 Aug 2020 23:13:02

US3362124

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 11 Aug 2021 22:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '21 Aug 2020 12:00'	System	21 Aug 2020 01:20:06

US3362124

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 11 Aug 2021 22:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 01:20:06

US3362124

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
Data entry locked.	System	21 Aug 2020 01:21:12
User entered 'Day 10'	System	21 Aug 2020 01:21:12

US3362124

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 11 Aug 2021 22:36:21

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-22T21:02:30', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'd76ccc21-3cf0-4e2f-bc9c-8b0879608968'	System	23 Aug 2020 02:02:37
User entered 'No interference with activity (1)'	System	23 Aug 2020 02:02:37

US3362124

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 11 Aug 2021 22:36:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-22T21:02:32', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'd76ccc21-3cf0-4e2f-bc9c-8b0879608968'	System	23 Aug 2020 02:02:37
User entered '22 Aug 2020 21:02'	System	23 Aug 2020 02:02:37

US3362124

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 11 Aug 2021 22:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 01:21:12

US3362124

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 11 Aug 2021 22:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 01:21:12

US3362124

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
Data entry locked.	System	21 Aug 2020 23:13:02
User entered 'Day 11'	System	21 Aug 2020 23:13:02

US3362124

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 11 Aug 2021 22:36:21

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-23T20:15:43', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '533f1b8d-917c-4faa-8727-5e7a1d424874' User entered 'None (0)'	System	24 Aug 2020 01:18:59
	System	24 Aug 2020 01:18:59

US3362124

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 11 Aug 2021 22:36:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-23T20:15:45', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '533f1b8d-917c-4faa-8727-5e7a1d424874' User entered '23 Aug 2020 20:15'	System	24 Aug 2020 01:18:59
	System	24 Aug 2020 01:18:59

US3362124

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 11 Aug 2021 22:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 23:13:02

US3362124

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 11 Aug 2021 22:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 23:13:02

US3362124

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
Data entry locked.	System	19 Aug 2020 02:49:06
User entered 'Day 8'	System	19 Aug 2020 02:49:06

US3362124

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:36:21

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 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-20T20:21:11', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '4c915fe5-491c-4b8c-988c-b4f0f40bf53d' User entered 'No (N)'	System	21 Aug 2020 01:21:17
	System	21 Aug 2020 01:21:17

US3362124

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:36:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-20T20:21:13', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '4c915fe5-491c-4b8c-988c-b4f0f40bf53d' User entered '20 Aug 2020 20:21'	System	21 Aug 2020 01:21:17
	System	21 Aug 2020 01:21:17

US3362124

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 02:49:06

US3362124

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 02:49:06

US3362124

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
Data entry locked.	System	21 Aug 2020 01:20:06
User entered 'Day 9'	System	21 Aug 2020 01:20:06

US3362124

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:36:21

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 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-21T18:13:02', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '3fa612b6-e0f3-436d-8c85-0a96b00ac695'	System	21 Aug 2020 23:13:08
User entered 'No (N)'	System	21 Aug 2020 23:13:08

US3362124

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:36:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-21T18:13:04', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '3fa612b6-e0f3-436d-8c85-0a96b00ac695'	System	21 Aug 2020 23:13:08
User entered '21 Aug 2020 18:13'	System	21 Aug 2020 23:13:08

US3362124

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '21 Aug 2020 12:00'	System	21 Aug 2020 01:20:06

US3362124

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 01:20:06

US3362124

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
Data entry locked.	System	21 Aug 2020 01:21:12
User entered 'Day 10'	System	21 Aug 2020 01:21:12

US3362124

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:36:21

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 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-22T21:02:35', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'afb23ae4-b9b3-4f77-92fe-217072ad45a0' User entered 'No (N)'	System	23 Aug 2020 02:02:41
	System	23 Aug 2020 02:02:41

US3362124

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:36:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-22T21:02:37', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'afb23ae4-b9b3-4f77-92fe-217072ad45a0' User entered '22 Aug 2020 21:02'	System	23 Aug 2020 02:02:41
	System	23 Aug 2020 02:02:41

US3362124

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 01:21:12

US3362124

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 01:21:12

US3362124

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
Data entry locked.	System	21 Aug 2020 23:13:02
User entered 'Day 11'	System	21 Aug 2020 23:13:02

US3362124

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:36:21

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 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-23T20:15:47', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '62336202-b55c-4f4e-bc48-dbdf6b5b5f0c' User entered 'No (N)'	System	24 Aug 2020 01:19:01
	System	24 Aug 2020 01:19:01

US3362124

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:36:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-08-23T20:15:49', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '62336202-b55c-4f4e-bc48-dbdf6b5b5f0c' User entered '23 Aug 2020 20:15'	System	24 Aug 2020 01:19:01
	System	24 Aug 2020 01:19:01

US3362124

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 23:13:02

US3362124

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 23:13:02

US3362124

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 22:01:20

US3362124

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:21

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	20 Nov 2020 14:57:58
Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	20 Nov 2020 14:57:58
User closed query 'The 'Date of Contact or Contact Attempt' is before the 'Date of Informed Consent'. Please review and reconcile.' (Site from System).	System	20 Nov 2020 14:57:58
User entered '20 Aug 2020' reason for change: Data Entry Error	Crystal Rowell (b) (4)	20 Nov 2020 14:57:58
User opened query 'The 'Date of Contact or Contact Attempt' is before the 'Date of Informed Consent'. Please review and reconcile.' (Site from System).	System	19 Nov 2020 22:04:23
User closed query 'The 'Date of Contact or Contact Attempt' is before the 'Date of Informed Consent'. Please review and reconcile.' (Site from System).	System	19 Nov 2020 22:02:59
User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	19 Nov 2020 22:00:07
User opened query 'The 'Date of Contact or Contact Attempt' is before the 'Date of Informed Consent'. Please review and reconcile.' (Site from System).	System	19 Nov 2020 22:00:07
User entered '10 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 22:00:07
User entered '20 Aug 2020'	(b) (4), (b) (6)	20 Aug 2020 22:01:20

US3362124

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	20 Aug 2020 22:01:20

US3362124

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 22:01:20

US3362124

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 22:01:26

US3362124

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User entered 'I'	System	20 Aug 2020 22:01:26

US3362124

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
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)	07 Sep 2020 21:54:27
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	03 Sep 2020 20:33:05
User entered 'No (N)'	Crystal Rowell (b) (4)	03 Sep 2020 20:33:05
	(b) (4)	

US3362124

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:21

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered empty.	Crystal Rowell (b) (4)	03 Sep 2020 20:33:05

US3362124

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered empty; reason for change Data Entry Error	Amy Thomassie (b) (4)	07 Sep 2020 21:54:27
User entered 'Contact Not Made (CONTACT NOT MADE)'	Crystal Rowell (b) (4)	03 Sep 2020 20:33:05

US3362124

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered 'in convalescent visits'	Crystal Rowell (b) (4)	03 Sep 2020 20:33:05

US3362124

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered 'Yes (Y)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	30 Sep 2020 15:24:01
User entered 'No (N)'	Amy Thomassie (b) (4)	22 Sep 2020 23:13:13

US3362124

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:25
User entered '1'	System	30 Sep 2020 15:24:01
User entered empty.	System	22 Sep 2020 23:13:13

US3362124

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
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	30 Sep 2020 15:27:14
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	30 Sep 2020 15:24:18
User entered 'No (N)'	Crystal Rowell (b) (4) (b) (4)	30 Sep 2020 15:24:18

US3362124

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:21

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered empty.	Crystal Rowell (b) (4)	30 Sep 2020 15:24:18

US3362124

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered empty; reason for change Data Entry Error	Crystal Rowell (b) (4)	30 Sep 2020 15:27:14
User entered 'Contact Not Made (CONTACT NOT MADE)'	Crystal Rowell (b) (4)	30 Sep 2020 15:24:18

US3362124

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered 'patient in illness visit'	Crystal Rowell (b) (4)	30 Sep 2020 15:24:18

US3362124

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	30 Sep 2020 15:24:49

US3362124

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User entered 'I'	System	30 Sep 2020 15:24:49

US3362124

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:36:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered 'No (N)'	Crystal Rowell (b) (4)	30 Sep 2020 15:24:58

US3362124

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered empty.	Crystal Rowell (b) (4)	30 Sep 2020 15:24:58

US3362124

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:36:21

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered empty.	Crystal Rowell (b) (4)	30 Sep 2020 15:24:58

US3362124

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:36:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User entered 'VISIT2'	System	30 Sep 2020 15:24:58

US3362124

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	30 Sep 2020 15:25:04

US3362124

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User entered 'I'	System	30 Sep 2020 15:25:04

US3362124

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered 'No (N)'	Crystal Rowell (b) (4)	30 Sep 2020 15:25:19

US3362124

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered empty.	Crystal Rowell (b) (4)	30 Sep 2020 15:25:19

US3362124

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered empty.	Crystal Rowell (b) (4)	30 Sep 2020 15:25:19

US3362124

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered 'illness visit'	Crystal Rowell (b) (4)	30 Sep 2020 15:25:19

US3362124

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	30 Sep 2020 15:25:33

US3362124

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User entered 'I'	System	30 Sep 2020 15:25:33

US3362124

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered 'No (N)'	Crystal Rowell (b) (4)	30 Sep 2020 15:25:48

US3362124

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered empty.	Crystal Rowell (b) (4)	30 Sep 2020 15:25:48

US3362124

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered empty.	Crystal Rowell (b) (4)	30 Sep 2020 15:25:48

US3362124

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered 'illness call'	Crystal Rowell (b) (4)	30 Sep 2020 15:25:48

US3362124

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	30 Sep 2020 15:25:54

US3362124

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User entered 'I'	System	30 Sep 2020 15:25:54

US3362124

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 17:19:30

US3362124

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:21

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered '2 Oct 2020'	(b) (4), (b) (6)	02 Oct 2020 17:19:30

US3362124

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:19:30

US3362124

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 17:19:30

US3362124

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:19:37

US3362124

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User entered 'I'	System	02 Oct 2020 17:19:37

US3362124

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:36:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 18:04:05

US3362124

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered '5 Oct 2020'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 18:04:05

US3362124

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:36:21

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 18:04:05

US3362124

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:36:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User entered 'VISIT3'	System	05 Oct 2020 18:04:05

US3362124

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 18:06:24

US3362124

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User closed query 'Per CDM: Please consider updating the Date format to DD-MMM-YYYY including 2 digits for the day (for example 01-JAN-1999). ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 01:59:08
Query 'Per CDM: Please consider updating the Date format to DD-MMM-YYYY including 2 digits for the day (for example 01-JAN-1999). ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 18:43:00
User entered '05 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 18:42:52
User opened query 'Per CDM: Please consider updating the Date format to DD-MMM-YYYY including 2 digits for the day (for example 01-JAN-1999). ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 18:13:49
User entered '5 Oct 2020'	(b) (4), (b) (6)	05 Oct 2020 18:06:24

US3362124

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered '09:25'	(b) (4), (b) (6)	05 Oct 2020 18:06:24

US3362124

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User entered '05 Oct 2020 09:25'	System	06 Nov 2020 18:42:52
User entered '5 Oct 2020 09:25'	System	05 Oct 2020 18:06:24

US3362124

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered '36.8' C	(b) (4), (b) (6)	05 Oct 2020 18:06:24

US3362124

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 18:06:24

US3362124

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 18:06:24

US3362124

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered '57'	(b) (4), (b) (6)	05 Oct 2020 18:06:24

US3362124

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User entered 'bpm'	System	05 Oct 2020 18:06:24

US3362124

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered '18'	(b) (4), (b) (6)	05 Oct 2020 18:06:24

US3362124

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User entered 'breaths/min'	System	05 Oct 2020 18:06:24

US3362124

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered '124'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 18:06:24

US3362124

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User entered 'mmHg'	System	05 Oct 2020 18:06:24

US3362124

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered '83'	(b) (4), (b) (6)	05 Oct 2020 18:06:24

US3362124

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User entered 'mmHg'	System	05 Oct 2020 18:06:24

US3362124

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06

US3362124

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06

US3362124

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:36:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 18:06:31

US3362124

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:36:21

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered '5 Oct 2020'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 18:06:31

US3362124

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:36:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 18:09:47

US3362124

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:36:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered '5 Oct 2020'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 18:09:47

US3362124

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:36:21

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered '09:30'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 18:09:47

US3362124

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:36:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User entered '5 Oct 2020 09:30'	System	05 Oct 2020 18:09:47

US3362124

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:02:27

US3362124

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User entered '1'	System	05 Oct 2020 17:02:27

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
Data entry locked.	System	13 Aug 2020 15:22:05
User entered 'Day 64'	System	13 Aug 2020 15:22:05

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-10-13T11:08:29', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '2953fdb3-8b52-4258-84df-cd67e85a4f85'	System	13 Oct 2020 16:08:44
User entered 'No (N)'	System	13 Oct 2020 16:08:44

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-10-13T11:08:33', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '2953fdb3-8b52-4258-84df-cd67e85a4f85'	System	13 Oct 2020 16:08:44
User entered 'No (N)'	System	13 Oct 2020 16:08:44

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-10-13T11:08:42', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '2953fdb3-8b52-4258-84df-cd67e85a4f85' User entered '13 Oct 2020 11:08:42'	System	13 Oct 2020 16:08:44
	System	13 Oct 2020 16:08:44

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
Data entry locked.	System	13 Aug 2020 15:22:05
User entered '13 Oct 2020 00:01'	System	13 Aug 2020 15:22:05

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
Data entry locked.	System	13 Aug 2020 15:22:05
User entered '17 Oct 2020 23:59'	System	13 Aug 2020 15:22:05

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:49:07
Data entry locked.	System	13 Aug 2020 15:22:05
User entered 'Day 71'	System	13 Aug 2020 15:22:05

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:49:07

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:49:07

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Please 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)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:49:07

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[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)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:49:07

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:49:07

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:49:07

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:49:07

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:49:07

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:49:07

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:49:07

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:49:07

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:49:07

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:49:07

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:49:07

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:49:07

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:49:07

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:49:07

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:49:07

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:49:07

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:49:07

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:49:07

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Please 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)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:49:07

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[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)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:49:07

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Please 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)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:49:07

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:49:07

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:49:07
Data entry locked.	System	13 Aug 2020 15:22:05
User entered '20 Oct 2020 00:01'	System	13 Aug 2020 15:22:05

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:49:07
Data entry locked.	System	13 Aug 2020 15:22:05
User entered '24 Oct 2020 23:59'	System	13 Aug 2020 15:22:05

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
Data entry locked.	System	13 Aug 2020 15:22:05
User entered 'Day 78'	System	13 Aug 2020 15:22:05

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-10-29T11:19:12', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '80869a98-2886-45c5-897f-4c43f49a15bf' User entered 'Yes (Y)'	System	29 Oct 2020 16:20:18
	System	29 Oct 2020 16:20:18

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-10-29T11:19:16', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '80869a98-2886-45c5-897f-4c43f49a15bf' User entered 'No (N)'	System	29 Oct 2020 16:20:18
	System	29 Oct 2020 16:20:18

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-10-29T11:19:24', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '80869a98-2886-45c5-897f-4c43f49a15bf'	System	29 Oct 2020 16:20:18
User entered 'Yes (Y)'	System	29 Oct 2020 16:20:18

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-10-29T11:19:47', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '80869a98-2886-45c5-897f-4c43f49a15bf' User entered '1'	System	29 Oct 2020 16:20:18
	System	29 Oct 2020 16:20:18

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-10-29T11:19:47', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '80869a98-2886-45c5-897f-4c43f49a15bf' User entered '0'	System	29 Oct 2020 16:20:18
	System	29 Oct 2020 16:20:18

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-10-29T11:19:47', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '80869a98-2886-45c5-897f-4c43f49a15bf' User entered '0'	System	29 Oct 2020 16:20:18
	System	29 Oct 2020 16:20:18

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-10-29T11:19:47', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '80869a98-2886-45c5-897f-4c43f49a15bf' User entered '0'	System	29 Oct 2020 16:20:18
	System	29 Oct 2020 16:20:18

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-10-29T11:19:47', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '80869a98-2886-45c5-897f-4c43f49a15bf' User entered '0'	System	29 Oct 2020 16:20:18
	System	29 Oct 2020 16:20:18

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-10-29T11:19:47', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '80869a98-2886-45c5-897f-4c43f49a15bf' User entered '1'	System	29 Oct 2020 16:20:18
	System	29 Oct 2020 16:20:18

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-10-29T11:19:47', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '80869a98-2886-45c5-897f-4c43f49a15bf' User entered '0'	System	29 Oct 2020 16:20:18
	System	29 Oct 2020 16:20:18

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-10-29T11:19:47', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '80869a98-2886-45c5-897f-4c43f49a15bf' User entered '0'	System	29 Oct 2020 16:20:18
	System	29 Oct 2020 16:20:18

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-10-29T11:19:47', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '80869a98-2886-45c5-897f-4c43f49a15bf' User entered '0'	System	29 Oct 2020 16:20:18
	System	29 Oct 2020 16:20:18

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-10-29T11:19:47', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '80869a98-2886-45c5-897f-4c43f49a15bf' User entered '0'	System	29 Oct 2020 16:20:18
	System	29 Oct 2020 16:20:18

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-10-29T11:19:47', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '80869a98-2886-45c5-897f-4c43f49a15bf' User entered '0'	System	29 Oct 2020 16:20:18
	System	29 Oct 2020 16:20:18

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-10-29T11:19:47', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '80869a98-2886-45c5-897f-4c43f49a15bf'	System	29 Oct 2020 16:20:18
User entered '1'	System	29 Oct 2020 16:20:18

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-10-29T11:19:47', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '80869a98-2886-45c5-897f-4c43f49a15bf'	System	29 Oct 2020 16:20:18
User entered '1'	System	29 Oct 2020 16:20:18

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-10-29T11:19:47', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '80869a98-2886-45c5-897f-4c43f49a15bf' User entered '0'	System	29 Oct 2020 16:20:18
	System	29 Oct 2020 16:20:18

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-10-29T11:19:47', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '80869a98-2886-45c5-897f-4c43f49a15bf' User entered '0'	System	29 Oct 2020 16:20:18
	System	29 Oct 2020 16:20:18

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-10-29T11:19:47', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '80869a98-2886-45c5-897f-4c43f49a15bf' User entered '0'	System	29 Oct 2020 16:20:18
	System	29 Oct 2020 16:20:18

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-10-29T11:19:47', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '80869a98-2886-45c5-897f-4c43f49a15bf' User entered '0'	System	29 Oct 2020 16:20:18
	System	29 Oct 2020 16:20:18

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Please 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)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-10-29T11:19:55', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '80869a98-2886-45c5-897f-4c43f49a15bf'	System	29 Oct 2020 16:20:18
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	29 Oct 2020 16:20:18

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-10-29T11:19:58', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '80869a98-2886-45c5-897f-4c43f49a15bf' User entered 'No (N)'	System	29 Oct 2020 16:20:18
	System	29 Oct 2020 16:20:18

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-10-29T11:20:06', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '80869a98-2886-45c5-897f-4c43f49a15bf' User entered '29 Oct 2020 11:20:06'	System	29 Oct 2020 16:20:18
	System	29 Oct 2020 16:20:18

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
Data entry locked.	System	13 Aug 2020 15:22:05
User entered '27 Oct 2020 00:01'	System	13 Aug 2020 15:22:05

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
Data entry locked.	System	13 Aug 2020 15:22:05
User entered '31 Oct 2020 23:59'	System	13 Aug 2020 15:22:05

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
Data entry locked.	System	13 Aug 2020 15:22:05
User entered 'Day 92'	System	13 Aug 2020 15:22:05

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-11-12T00:23:47', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '40b517a1-3f7e-462e-9f21-4284174d7b0f'	System	12 Nov 2020 06:23:58
User entered 'No (N)'	System	12 Nov 2020 06:23:58

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-11-12T00:23:50', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '40b517a1-3f7e-462e-9f21-4284174d7b0f' User entered 'No (N)'	System	12 Nov 2020 06:23:58
	System	12 Nov 2020 06:23:58

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-11-12T00:23:53', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '40b517a1-3f7e-462e-9f21-4284174d7b0f' User entered '12 Nov 2020 00:23:53'	System	12 Nov 2020 06:23:58
	System	12 Nov 2020 06:23:58

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
Data entry locked.	System	13 Aug 2020 15:22:05
User entered '10 Nov 2020 00:01'	System	13 Aug 2020 15:22:05

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:56
Data entry locked.	System	13 Aug 2020 15:22:05
User entered '14 Nov 2020 23:59'	System	13 Aug 2020 15:22:05

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:49:07
Data entry locked.	System	13 Aug 2020 15:22:05
User entered 'Day 99'	System	13 Aug 2020 15:22:05

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:49:07

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:49:07

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Please 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)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:49:07

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[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)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:49:07

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:49:07

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:49:07

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:49:07

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:49:07

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:49:07

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:49:07

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:49:07

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:49:07

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:49:07

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:49:07

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:49:07

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:49:07

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:49:07

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:49:07

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:49:07

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:49:07

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:49:07

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Please 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)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:49:07

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[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)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:49:07

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Please 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)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:49:07

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:49:07

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:49:07
Data entry locked.	System	13 Aug 2020 15:22:05
User entered '17 Nov 2020 00:01'	System	13 Aug 2020 15:22:05

US3362124

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:49:07
Data entry locked.	System	13 Aug 2020 15:22:05
User entered '21 Nov 2020 23:59'	System	13 Aug 2020 15:22:05

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[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 (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-12-05T10:52:10', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'bf90f408-85cb-4089-b0d5-bf8453e656ce'	System	05 Dec 2020 16:52:57
User entered 'No (N)'	System	05 Dec 2020 16:52:57

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

Have you been exposed to someone with 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 (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-12-05T10:52:49', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'bf90f408-85cb-4089-b0d5-bf8453e656ce'	System	05 Dec 2020 16:52:57
User entered 'No (N)'	System	05 Dec 2020 16:52:57

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-12-05T10:52:51', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'bf90f408-85cb-4089-b0d5-bf8453e656ce' User entered '05 Dec 2020 10:52:51'	System	05 Dec 2020 16:52:57
	System	05 Dec 2020 16:52:57

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[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 (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-12-22T13:11:14', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'f9053c97-5fa7-4ad9-8580-7540160b0a71' User entered 'No (N)'	System	22 Dec 2020 19:11:23
	System	22 Dec 2020 19:11:23

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

Have you been exposed to someone with 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 (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-12-22T13:11:16', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'f9053c97-5fa7-4ad9-8580-7540160b0a71' User entered 'No (N)'	System	22 Dec 2020 19:11:23
	System	22 Dec 2020 19:11:23

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-12-22T13:11:19', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'f9053c97-5fa7-4ad9-8580-7540160b0a71' User entered '22 Dec 2020 13:11:19'	System	22 Dec 2020 19:11:23
	System	22 Dec 2020 19:11:23

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[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 (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-12-26T23:02:50', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'faab40a4-0e82-4895-be8e-26e07a661f83' User entered 'No (N)'	System	27 Dec 2020 05:03:15
	System	27 Dec 2020 05:03:15

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

Have you been exposed to someone with 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 (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-12-26T23:02:52', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'faab40a4-0e82-4895-be8e-26e07a661f83'	System	27 Dec 2020 05:03:15
User entered 'No (N)'	System	27 Dec 2020 05:03:15

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2020-12-26T23:02:55', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'faab40a4-0e82-4895-be8e-26e07a661f83' User entered '26 Dec 2020 23:02:55'	System	27 Dec 2020 05:03:15
	System	27 Dec 2020 05:03:15

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[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 (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2021-01-09T11:08:58', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'ba0f6edc-37f9-4a1a-b848-7d37700d66d5' User entered 'No (N)'	System	09 Jan 2021 17:09:06
	System	09 Jan 2021 17:09:06

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

Have you been exposed to someone with 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 (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2021-01-09T11:09:00', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'ba0f6edc-37f9-4a1a-b848-7d37700d66d5'	System	09 Jan 2021 17:09:06
User entered 'No (N)'	System	09 Jan 2021 17:09:06

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2021-01-09T11:09:02', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'ba0f6edc-37f9-4a1a-b848-7d37700d66d5' User entered '09 Jan 2021 11:09:02'	System	09 Jan 2021 17:09:06
	System	09 Jan 2021 17:09:06

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[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 (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2021-01-19T11:03:33', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'f60e3914-e0bd-456f-8b92-47e314f9c771' User entered 'No (N)'	System	19 Jan 2021 17:04:40
	System	19 Jan 2021 17:04:40

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

Have you been exposed to someone with 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 (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2021-01-19T11:03:35', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'f60e3914-e0bd-456f-8b92-47e314f9c771'	System	19 Jan 2021 17:04:40
User entered 'No (N)'	System	19 Jan 2021 17:04:40

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2021-01-19T11:03:37', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'f60e3914-e0bd-456f-8b92-47e314f9c771' User entered '19 Jan 2021 11:03:37'	System	19 Jan 2021 17:04:40
	System	19 Jan 2021 17:04:40

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[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 (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2021-01-26T00:11:16', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'c9b5cb4a-d481-4dc9-a9dd-a71bddb9d4c5'	System	26 Jan 2021 06:11:23
User entered 'No (N)'	System	26 Jan 2021 06:11:23

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

Have you been exposed to someone with 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 (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2021-01-26T00:11:19', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'c9b5cb4a-d481-4dc9-a9dd-a71bddb9d4c5'	System	26 Jan 2021 06:11:23
User entered 'No (N)'	System	26 Jan 2021 06:11:23

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2021-01-26T00:11:21', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'c9b5cb4a-d481-4dc9-a9dd-a71bddb9d4c5' User entered '26 Jan 2021 00:11:21'	System	26 Jan 2021 06:11:23
	System	26 Jan 2021 06:11:23

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[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 (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2021-01-30T18:41:39', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '3b482af9-a103-4f46-9fb7-8f41a8c4f93e' User entered 'No (N)'	System	03 Feb 2021 16:31:09
	System	03 Feb 2021 16:31:09

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

Have you been exposed to someone with 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 (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2021-01-30T18:41:41', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '3b482af9-a103-4f46-9fb7-8f41a8c4f93e' User entered 'No (N)'	System	03 Feb 2021 16:31:09

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2021-01-30T18:41:43', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '3b482af9-a103-4f46-9fb7-8f41a8c4f93e' User entered '30 Jan 2021 18:41:43'	System	03 Feb 2021 16:31:09
	System	03 Feb 2021 16:31:09

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[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 (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2021-02-07T09:56:42', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'cd71e6a9-eeda-4b2d-8a73-76b00e14d1e6' User entered 'No (N)'	System	07 Feb 2021 15:56:49
	System	07 Feb 2021 15:56:49

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

Have you been exposed to someone with 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 (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2021-02-07T09:56:45', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'cd71e6a9-eeda-4b2d-8a73-76b00e14d1e6' User entered 'No (N)'	System	07 Feb 2021 15:56:49

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2021-02-07T09:56:47', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'cd71e6a9-eeda-4b2d-8a73-76b00e14d1e6' User entered '07 Feb 2021 09:56:47'	System	07 Feb 2021 15:56:49
	System	07 Feb 2021 15:56:49

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[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 (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2021-02-13T17:09:11', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '7e1927c3-2e31-4854-8ed1-6340f672c960' User entered 'No (N)'	System	13 Feb 2021 23:13:55
	System	13 Feb 2021 23:13:55

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

Have you been exposed to someone with 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 (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2021-02-13T17:09:12', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '7e1927c3-2e31-4854-8ed1-6340f672c960'	System	13 Feb 2021 23:13:55
User entered 'No (N)'	System	13 Feb 2021 23:13:55

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2021-02-13T17:09:14', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '7e1927c3-2e31-4854-8ed1-6340f672c960'	System	13 Feb 2021 23:13:55
User entered '13 Feb 2021 17:09:14'	System	13 Feb 2021 23:13:55

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[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 (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2021-02-28T17:06:05-06:00', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'd09f2f38-4b76-4fe6-9078-a4c8fca134fa' User entered 'No (N)'	System	28 Feb 2021 23:11:56

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

Have you been exposed to someone with 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 (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2021-02-28T17:06:07-06:00', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'd09f2f38-4b76-4fe6-9078-a4c8fca134fa' User entered 'No (N)'	System	28 Feb 2021 23:11:56

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2021-02-28T17:06:09-06:00', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'd09f2f38-4b76-4fe6-9078-a4c8fca134fa' User entered '28 Feb 2021 23:06:09'	System	28 Feb 2021 23:11:56
	System	28 Feb 2021 23:11:56

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[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 (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2021-03-08T09:20:47-06:00', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '9e667dde-8f11-4167-84f9-fd113387a03c'	System	08 Mar 2021 15:20:53
User entered 'No (N)'	System	08 Mar 2021 15:20:53

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

Have you been exposed to someone with 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 (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2021-03-08T09:20:49-06:00', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '9e667dde-8f11-4167-84f9-fd113387a03c'	System	08 Mar 2021 15:20:53
User entered 'No (N)'	System	08 Mar 2021 15:20:53

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2021-03-08T09:20:51-06:00', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '9e667dde-8f11-4167-84f9-fd113387a03c' User entered '08 Mar 2021 15:20:51'	System	08 Mar 2021 15:20:53
	System	08 Mar 2021 15:20:53

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[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 (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2021-03-17T01:23:06-05:00', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '3ec99534-ffcf-42de-8bd9-a288bb53e140'	System	17 Mar 2021 06:23:12
User entered 'No (N)'	System	17 Mar 2021 06:23:12

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

Have you been exposed to someone with 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 (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2021-03-17T01:23:08-05:00', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '3ec99534-ffcf-42de-8bd9-a288bb53e140'	System	17 Mar 2021 06:23:12
User entered 'No (N)'	System	17 Mar 2021 06:23:12

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2021-03-17T01:23:10-05:00', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '3ec99534-ffcf-42de-8bd9-a288bb53e140'	System	17 Mar 2021 06:23:12
User entered '17 Mar 2021 01:23:10'	System	17 Mar 2021 06:23:12

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[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 (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2021-03-29T00:33:15-05:00', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'a8e5e789-e7f5-4231-a7a2-dbda1bebebc8'	System	29 Mar 2021 05:33:21
User entered 'No (N)'	System	29 Mar 2021 05:33:21

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

Have you been exposed to someone with 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 (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2021-03-29T00:33:17-05:00', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'a8e5e789-e7f5-4231-a7a2-dbd1bebebc8'	System	29 Mar 2021 05:33:21
User entered 'No (N)'	System	29 Mar 2021 05:33:21

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2021-03-29T00:33:19-05:00', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'a8e5e789-e7f5-4231-a7a2-dbda1bebebc8' User entered '29 Mar 2021 00:33:19'	System	29 Mar 2021 05:33:21
	System	29 Mar 2021 05:33:21

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[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 (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2021-04-11T19:46:01-05:00', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '5bbaceb9-479b-44f5-a9f2-318b2df55b3e' User entered 'No (N)'	System	12 Apr 2021 00:46:06
	System	12 Apr 2021 00:46:06

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

Have you been exposed to someone with 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 (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2021-04-11T19:46:02-05:00', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '5bbaceb9-479b-44f5-a9f2-318b2df55b3e' User entered 'No (N)'	System	12 Apr 2021 00:46:06

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2021-04-11T19:46:04-05:00', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '5bbaceb9-479b-44f5-a9f2-318b2df55b3e'	System	12 Apr 2021 00:46:06
User entered '11 Apr 2021 19:46:04'	System	12 Apr 2021 00:46:06

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[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 (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2021-04-21T01:12:24-05:00', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'f422933b-e2d8-4f5d-aa50-d4d7b4c7c1e9' User entered 'No (N)'	System	21 Apr 2021 06:12:30
	System	21 Apr 2021 06:12:30

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

Have you been exposed to someone with 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 (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2021-04-21T01:12:26-05:00', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'f422933b-e2d8-4f5d-aa50-d4d7b4c7c1e9' User entered 'No (N)'	System	21 Apr 2021 06:12:30

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2021-04-21T01:12:28-05:00', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: 'f422933b-e2d8-4f5d-aa50-d4d7b4c7c1e9'	System	21 Apr 2021 06:12:30
User entered '21 Apr 2021 01:12:28'	System	21 Apr 2021 06:12:30

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '15 Oct 2022 00:01'	System	19 Nov 2020 05:49:07

US3362124

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:07
Amendment Manager: User entered '19 Oct 2022 23:59'	System	19 Nov 2020 05:49:07

US3362124

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:36:21

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 10:42:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2021-02-28T17:06:13-06:00', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '9544f238-b9df-49da-9323-d98509203cfa'	System	28 Feb 2021 23:11:58
User entered 'No (N)'	System	28 Feb 2021 23:11:58

US3362124

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:36:21

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76A8892A-3C11-4A80-AC73-FC81EAFE27D4)', Time: '2021-02-28T17:06:15-06:00', User OID: 'PatientReportedOutcome (US3362124)', ODM File OID: '9544f238-b9df-49da-9323-d98509203cfa' User entered '28 Feb 2021 23:06:15'	System	28 Feb 2021 23:11:58
	System	28 Feb 2021 23:11:58

US3362124

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User signature succeeded.	Jordan Whatley (b) (4)	06 Mar 2021 04:20:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 21:48:55

US3362124

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:21

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User signature succeeded.	Jordan Whatley (b) (4)	06 Mar 2021 04:20:44
User entered '03 Nov 2020'	(b) (4), (b) (6)	03 Nov 2020 21:48:55

US3362124

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User signature succeeded.	Jordan Whatley (b) (4)	06 Mar 2021 04:20:44
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 21:48:55

US3362124

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User signature succeeded.	Jordan Whatley (b) (4)	06 Mar 2021 04:20:44
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 21:48:55

US3362124

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User signature succeeded.	Jordan Whatley (b) (4)	06 Mar 2021 04:20:44
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:51:43
DataPoint Verified.		19 Nov 2020 17:51:40
User entered 'Yes (Y)'		03 Nov 2020 21:48:59

US3362124

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:06
User entered 'I'	System	03 Nov 2020 21:48:59

US3362124

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:44:00
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Dec 2020 16:47:22

US3362124

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:21

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:44:00
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
User entered '9 Dec 2020'	(b) (4), (b) (6)	09 Dec 2020 16:47:22

US3362124

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:44:00
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	09 Dec 2020 16:47:22

US3362124

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:44:00
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
User entered empty.	(b) (4), (b) (6)	09 Dec 2020 16:47:22

US3362124

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:44:00
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Dec 2020 16:47:30

US3362124

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:44:00
User entered 'I'	System	09 Dec 2020 16:47:30

US3362124

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:44:00
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Jan 2021 21:55:57

US3362124

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:44:00
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
User entered '06 Jan 2021'	(b) (4), (b) (6)	06 Jan 2021 21:55:57

US3362124

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:44:00
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	06 Jan 2021 21:55:57

US3362124

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:44:00
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
User entered empty.	(b) (4), (b) (6)	06 Jan 2021 21:55:57

US3362124

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:44:00
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Jan 2021 21:56:02

US3362124

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:44:00
User entered 'I'	System	06 Jan 2021 21:56:02

US3362124

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:44:00
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
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)	23 Feb 2021 18:31:59
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	23 Feb 2021 18:31:35
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 18:31:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Feb 2021 18:03:22

US3362124

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:21

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:44:00
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 18:31:35
User entered '04 Feb 2021'	(b) (4), (b) (6)	23 Feb 2021 18:03:22

US3362124

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:44:00
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
User entered empty; reason for change New Information	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:31:59
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: New Information		23 Feb 2021 18:31:35
User entered 'Contact Made (CONTACT MADE)'		23 Feb 2021 18:03:22

US3362124

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:44:00
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided.	(b) (4)	23 Feb 2021 18:31:59
Please review and reconcile.' (Site from System).	System	
User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided.	System	23 Feb 2021 18:31:35
Please review and reconcile.' (Site from System).		
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 18:03:22

US3362124

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:44:00
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Feb 2021 18:03:26

US3362124

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:44:00
User entered 'I'	System	23 Feb 2021 18:03:26

US3362124

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:36:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:46
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Feb 2021 18:32:48

US3362124

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:46
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:20
User entered '23 Feb 2021'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:32:48

US3362124

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:36:21

[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 08:34:46
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:20
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	23 Feb 2021 18:32:48

US3362124

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:36:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:46
User entered 'VISIT4'	System	23 Feb 2021 18:32:48

US3362124

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:46
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:20
User closed query 'Per CDM: Thank you for the response. Since both visits occurred on the same day, it is expected to have the same information recorded. Please consider adding the vital signs information (pre-dose or post-dose) for this visit. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:15:09
Query 'Per CDM: Thank you for the response. Since both visits occurred on the same day, it is expected to have the same information recorded. Please consider adding the vital signs information (pre-dose or post-dose) for this visit. ' answered with 'updated' (Site from DM).	Alexandra Caillouet (b) (4)	07 Apr 2021 13:33:07
User entered 'Yes (Y)' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	07 Apr 2021 13:32:46
User opened query 'Per CDM: Thank you for the response. Since both visits occurred on the same day, it is expected to have the same information recorded. Please consider adding the vital signs information (pre-dose or post-dose) for this visit. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 17:42:07
User closed query 'Per CDM: Please be aware that Visit 4 Day 209 and OL-D29 took place exactly the same day. However, "Vital Signs" is recorded here as NO but in OL-D29 it is recorded as YES. Please clarify why there is a difference or update the field. Thank you! ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 17:42:07
Query 'Per CDM: Please be aware that Visit 4 Day 209 and OL-D29 took place exactly the same day. However, "Vital Signs" is recorded here as NO but in OL-D29 it is recorded as YES. Please clarify why there is a difference or update the field. Thank you! ' answered with 'Vitals not required per protocol for visit 4.' (Site from DM).	Alexandra Caillouet (b) (4)	05 Apr 2021 19:44:01

US3362124

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Please be aware that Visit 4 Day 209 and OL-D29 took place exactly the same day. However, "Vital Signs" is recorded here as NO but in OL-D29 it is recorded as YES. Please clarify why there is a difference or update the field. Thank you! ' (Site from DM). User entered 'No (N)'	(b) (4), (b) (6) Alexandra Caillouet (b) (4)	05 Apr 2021 19:35:13 30 Mar 2021 18:44:00

US3362124

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:46
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:20
User entered '23 Feb 2021' reason for change: Data Entry Error	(b) (4)	07 Apr 2021 13:32:46
User entered empty.	Alexandra Caillouet	30 Mar 2021 18:44:00
	(b) (4)	

US3362124

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:46
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:20
User entered '09:15' reason for change: Data Entry Error	(b) (4)	07 Apr 2021 13:32:46
User entered empty.	Alexandra Caillouet	30 Mar 2021 18:44:00
	(b) (4)	

US3362124

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:46
User entered '23 Feb 2021 09:15'	System	07 Apr 2021 13:32:46
User entered empty.	System	30 Mar 2021 18:44:00

US3362124

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:46
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:20
User entered '37.0' C reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	07 Apr 2021 13:32:46
User entered empty.	Alexandra Caillouet (b) (4)	30 Mar 2021 18:44:00

US3362124

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:46
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:20
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	07 Apr 2021 13:32:46
User entered empty.	Alexandra Caillouet	30 Mar 2021 18:44:00
	(b) (4)	

US3362124

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:46
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:20
User entered empty.	Alexandra Caillouet (b) (4)	30 Mar 2021 18:44:00

US3362124

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:46
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:20
User entered '76' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	07 Apr 2021 13:32:46
User entered empty.	Alexandra Caillouet (b) (4)	30 Mar 2021 18:44:00

US3362124

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:46
User entered 'bpm'	System	07 Apr 2021 13:32:46
User entered empty.	System	30 Mar 2021 18:44:00

US3362124

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:46
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:20
User entered '16' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	07 Apr 2021 13:32:46
User entered empty.	Alexandra Caillouet (b) (4)	30 Mar 2021 18:44:00

US3362124

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:46
User entered 'breaths/min'	System	07 Apr 2021 13:32:46
User entered empty.	System	30 Mar 2021 18:44:00

US3362124

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:46
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:20
User entered '124' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	07 Apr 2021 13:32:46
User entered empty.	Alexandra Caillouet (b) (4)	30 Mar 2021 18:44:00

US3362124

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:46
User entered 'mmHg'	System	07 Apr 2021 13:32:46
User entered empty.	System	30 Mar 2021 18:44:00

US3362124

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:46
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:20
User entered '69' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	07 Apr 2021 13:32:46
User entered empty.	Alexandra Caillouet (b) (4)	30 Mar 2021 18:44:00

US3362124

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:46
User entered 'mmHg'	System	07 Apr 2021 13:32:46
User entered empty.	System	30 Mar 2021 18:44:00

US3362124

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:46

US3362124

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:46

US3362124

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:36:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:46
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:20
User entered 'No (N)'	(b) (4), (b) (6)	23 Feb 2021 18:39:47

US3362124

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:36:21

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:46
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:20
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 18:39:47

US3362124

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:36:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:46
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:20
User closed query 'Per CDM: Please be aware that Visit 4 and OL-D29 took place exactly the same day. However, "Immunogenicity Assessment" is recorded here as NO but in OL-D29 it is captured. Please clarify why there is a difference or update the field. Thank you!' ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:26:14
Query 'Per CDM: Please be aware that Visit 4 and OL-D29 took place exactly the same day. However, "Immunogenicity Assessment" is recorded here as NO but in OL-D29 it is captured. Please clarify why there is a difference or update the field. Thank you!' ' answered with 'visit 4 ad OL-d29 were combined therefore draw times are same and will be labeled as OL-d29' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 19:56:20
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 19:55:15
User opened query 'Per CDM: Please be aware that Visit 4 and OL-D29 took place exactly the same day. However, "Immunogenicity Assessment" is recorded here as NO but in OL-D29 it is captured. Please clarify why there is a difference or update the field. Thank you!' ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 19:34:48
User entered 'No (N)'	Amy Thomassie (b) (4) (b) (4)	19 Mar 2021 20:57:05

US3362124

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:36:21

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:46
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:20
User entered '23 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 19:55:15
User entered empty.	Amy Thomassie (b) (4)	19 Mar 2021 20:57:05

US3362124

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:36:21

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:46
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:20
User entered '09:23' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 19:55:15
User entered empty.	Amy Thomassie (b) (4)	19 Mar 2021 20:57:05

US3362124

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:36:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:46
User entered '23 Feb 2021 09:23'	System	05 Apr 2021 19:55:15
User entered empty.	System	19 Mar 2021 20:57:05

US3362124

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:46
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Feb 2021 18:39:50

US3362124

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:46
User entered 'I'	System	23 Feb 2021 18:39:50

US3362124

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard unlocked.	KC Joubran (b) (4)	02 May 2021 20:12:07
Data hard locked.	(b) (4) (b) (4), (b) (6)	02 May 2021 15:18:32
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:21:06

US3362124

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:21

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	KC Joubran (b) (4)	02 May 2021 20:12:07
Data hard locked.	(b) (4) (b) (4), (b) (6)	02 May 2021 15:18:32
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:20
User entered '7 Apr 2021'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:21:06

US3362124

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard unlocked.	KC Joubran (b) (4)	02 May 2021 20:12:07
Data hard locked.	(b) (4) (b) (4), (b) (6)	02 May 2021 15:18:32
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:21:06

US3362124

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard unlocked.	KC Joubran (b) (4)	02 May 2021 20:12:07
Data hard locked.	(b) (4) (b) (4), (b) (6)	02 May 2021 15:18:32
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:20
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:21:06

US3362124

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard unlocked.	KC Joubran (b) (4)	02 May 2021 20:12:14
Data hard locked.	(b) (4) (b) (4), (b) (6)	02 May 2021 15:18:32
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:21:10

US3362124

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard unlocked.	KC Joubran (b) (4)	02 May 2021 20:12:14
Data hard locked.	(b) (4) (b) (4), (b) (6)	02 May 2021 15:18:32
User entered 'I'	System	07 Apr 2021 21:21:10

US3362124

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:36:21

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:51:20
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:04:15
User entered '18 Sep 2020'	Alexandra Caillouet (b) (4)	18 Mar 2021 20:31:23

US3362124

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:36:21

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:51:20
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:04:15
User entered '14:47'	Alexandra Caillouet (b) (4)	18 Mar 2021 20:31:23

US3362124

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:36:21

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:51:20
User entered '18 Sep 2020 14:47'	System	18 Mar 2021 20:31:23

US3362124

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:36:21

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:51:20
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:04:15
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	Alexandra Caillouet	18 Mar 2021 20:31:23
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:36:21

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:51:20
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:04:15
User entered 'Yes (Y)' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	18 Mar 2021 20:31:29
User entered 'No (N)'	Alexandra Caillouet (b) (4)	18 Mar 2021 20:31:23

US3362124

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:51:24
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
User entered 'Day 28 (Day 28)'	Alexandra Caillouet (b) (4)	18 Mar 2021 20:32:26

US3362124

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:51:24
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:04:20
User entered '18 Sep 2020'	Alexandra Caillouet	18 Mar 2021 20:32:26
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:51:24
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:04:20
User entered '0'	Alexandra Caillouet (b) (4)	18 Mar 2021 20:32:26

US3362124

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:51:24
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:04:20
User entered '99'	Alexandra Caillouet (b) (4)	18 Mar 2021 20:32:26

US3362124

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:51:24
User entered '%'	System	18 Mar 2021 20:32:26

US3362124

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:51:24
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:04:20
User entered '37.1' C	Alexandra Caillouet	18 Mar 2021 20:32:26
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:51:24
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:04:20
User entered 'None (None)'	Alexandra Caillouet (b) (4)	18 Mar 2021 20:32:26

US3362124

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:51:24
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:04:20
User entered 'None (None)'	Alexandra Caillouet (b) (4)	18 Mar 2021 20:32:26

US3362124

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:51:24
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:04:20
User entered 'None (None)'	Alexandra Caillouet (b) (4)	18 Mar 2021 20:32:26

US3362124

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:51:24
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:04:20
User entered 'None (None)'	Alexandra Caillouet	18 Mar 2021 20:32:26
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:51:24
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:04:20
User entered 'None (None)'	Alexandra Caillouet (b) (4)	18 Mar 2021 20:32:26

US3362124

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:51:24
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:04:20
User entered 'None (None)'	Alexandra Caillouet (b) (4)	18 Mar 2021 20:32:26

US3362124

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:51:24
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:04:20
User entered 'None (None)'	Alexandra Caillouet (b) (4)	18 Mar 2021 20:32:26

US3362124

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:51:24
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:04:20
User entered 'None (None)'	Alexandra Caillouet (b) (4)	18 Mar 2021 20:32:26

US3362124

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:51:24
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:04:20
User entered 'None (None)'	Alexandra Caillouet (b) (4)	18 Mar 2021 20:32:26

US3362124

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:51:24
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:04:20
User entered 'None (None)'	Alexandra Caillouet (b) (4)	18 Mar 2021 20:32:26

US3362124

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:51:24
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:04:20
User entered 'None (None)'	Alexandra Caillouet (b) (4)	18 Mar 2021 20:32:26

US3362124

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:51:24
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:04:20
User entered 'None (None)'	Alexandra Caillouet (b) (4)	18 Mar 2021 20:32:26

US3362124

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:51:24
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:04:20
User entered 'None (None)'	Alexandra Caillouet (b) (4)	18 Mar 2021 20:32:26

US3362124

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:51:24
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:04:20
User entered 'None (None)'	Alexandra Caillouet	18 Mar 2021 20:32:26
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:51:24
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:04:20
User entered 'None (None)'	Alexandra Caillouet (b) (4)	18 Mar 2021 20:32:26

US3362124

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:51:24
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:04:20
User entered 'None (None)'	Alexandra Caillouet (b) (4)	18 Mar 2021 20:32:26

US3362124

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:36:21

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:51:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:04:35
User entered '18 Sep 2020'	Alexandra Caillouet (b) (4)	18 Mar 2021 20:34:48

US3362124

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:36:21

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:51:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:04:35
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	18 Mar 2021 20:34:48

US3362124

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:36:21

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:51:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:04:35
User entered 'No (N)'	Alexandra Caillouet (b) (4)	18 Mar 2021 20:34:48

US3362124

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:36:21

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:51:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:04:35
User entered '18 Sep 2020'	Alexandra Caillouet (b) (4)	18 Mar 2021 20:34:48

US3362124

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:36:21

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:51:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:04:35
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Alexandra Caillouet (b) (4)	18 Mar 2021 20:34:48

US3362124

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:36:21

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:51:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:04:35
User entered empty.	Alexandra Caillouet (b) (4)	18 Mar 2021 20:34:48

US3362124

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:36:21

[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)	02 May 2021 07:51:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:04:35
User entered 'No (N)'	Alexandra Caillouet (b) (4)	18 Mar 2021 20:34:48

US3362124

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:36:21

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:51:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:04:35
User entered empty.	Alexandra Caillouet (b) (4)	18 Mar 2021 20:34:48

US3362124

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:36:21

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:51:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:04:35
User entered empty.	Alexandra Caillouet (b) (4)	18 Mar 2021 20:34:48

US3362124

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:36:21

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:51:29
User entered '0'	System	18 Mar 2021 20:34:48

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:36:21

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:51
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
User closed query 'Per GCL Lab Reconciliation requery: Swab: Per response, "Nasal Swab from 18SEP2020 was for subject's Day 28 Illness visit 2, but an illness day 1 kit was accidentally used.", per Preclarus, two swab sample with requisition kit ID # 1F602924602, dated 18-SEP-2020 is present, one labelled with accession # 1F606577338 under illness D1 visit & another with accession # 1F617042034 under illness D28 visit & per EDC, it is recorded under Covid-19 Assessment. Per protocol, either swab or saliva is collected at Day 28 and it is to be recorded under Saliva Collection Log Day 28. Kindly update Covid-19 Assessment 18 Sep 2020 eCRF as appropriate & record data under Saliva Collection Log Day 28, else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Apr 2021 04:59:21
Query 'Per GCL Lab Reconciliation requery: Swab: Per response, "Nasal Swab from 18SEP2020 was for subject's Day 28 Illness visit 2, but an illness day 1 kit was accidentally used.", per Preclarus, two swab sample with requisition kit ID # 1F602924602, dated 18-SEP-2020 is present, one labelled with accession # 1F606577338 under illness D1 visit & another with accession # 1F617042034 under illness D28 visit & per EDC, it is recorded under Covid-19 Assessment. Per protocol, either swab or saliva is collected at Day 28 and it is to be recorded under Saliva Collection Log Day 28. Kindly update Covid-19 Assessment 18 Sep 2020 eCRF as appropriate & record data under Saliva Collection Log Day 28, else clarify.' answered with 'updated per query' (Site from DM).	Amy Thomassie (b) (4) (b) (4)	09 Apr 2021 14:12:17

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:36:21

[Date of Contact](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation requery: Swab: Per response, "Nasal Swab from 18SEP2020 was for subject's Day 28 Illness visit 2, but an illness day 1 kit was accidentally used.", per Preclarus, two swab sample with requisition kit ID # 1F602924602, dated 18-SEP-2020 is present, one labelled with accession # 1F606577338 under illness D1 visit & another with accession # 1F617042034 under illness D28 visit & per EDC, it is recorded under Covid-19 Assessment. Per protocol, either swab or saliva is collected at Day 28 and it is to be recorded under Saliva Collection Log Day 28. Kindly update Covid-19 Assessment 18 Sep 2020 eCRF as appropriate & record data under Saliva Collection Log Day 28, else clarify.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 13:09:11
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 18-Sep-2020 is reported as an Illness Visit sample in PPD Central Labs however, data is missing in EDC. Kindly review if the swab sample was collected, if yes, consider updating EDC by initiating Covid -19 Assessment eCRF for the corresponding date and updating Swab data in the COVID Diagnostic form. Else clarify.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 13:09:11
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 18-Sep-2020 is reported as an Illness Visit sample in PPD Central Labs however, data is missing in EDC. Kindly review if the swab sample was collected, if yes, consider updating EDC by initiating Covid -19 Assessment eCRF for the corresponding date and updating Swab data in the COVID Diagnostic form. Else clarify.' answered with 'Nasal Swab from 18SEP2020 was for subject's Day 28 Illness visit 2, but an illness day 1 kit was accidentally used. ' (Site from DM).	Alexandra Caillouet (b) (4)	18 Mar 2021 20:29:13

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:36:21

[Date of Contact](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 18-Sep-2020 is reported as an Illness Visit sample in PPD Central Labs however, data is missing in EDC. Kindly review if the swab sample was collected, if yes, consider updating EDC by initiating Covid -19 Assessment eCRF for the corresponding date and updating Swab data in the COVID Diagnostic form. Else clarify.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 11:27:25
	(b) (4), (b) (6)	04 Nov 2020 20:33:15
User entered '21 Aug 2020'	Crystal Rowell (b) (4)	26 Aug 2020 18:13:00
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:36:21

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:51
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:33:15
User entered '09:00'	(b) (4), (b) (6)	
	Crystal Rowell (b) (4)	26 Aug 2020 18:13:00
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:36:21

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:51
User entered '21 Aug 2020 09:00'	System	26 Aug 2020 18:13:00

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:36:21

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:51
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:33:15
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Crystal Rowell (b) (4) (b) (4)	26 Aug 2020 18:13:00

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:36:21

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:51
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:33:15
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	26 Aug 2020 18:13:00

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
User entered 'Day 4 (Day 4)' reason for change:	(b) (4)	
Data Entry Error	Alexandra Caillouet	02 Dec 2020 14:25:20
User entered 'Day 1 (Day 1)'	(b) (4)	
	Crystal Rowell (b) (4)	26 Aug 2020 18:14:42
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
User closed query 'Per CDM; Please confirm initial start date of symptoms and Contact Date are the same (21AUG2020) or update accordingly' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 07:01:12
Query 'Per CDM; Please confirm initial start date of symptoms and Contact Date are the same (21AUG2020) or update accordingly' answered with 'confirmed ' (Site from DM).	Alexandra Caillouet (b) (4)	09 Nov 2020 18:30:20
User opened query 'Per CDM; Please confirm initial start date of symptoms and Contact Date are the same (21AUG2020) or update accordingly' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 03:45:47
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered '21 Aug 2020'	Crystal Rowell (b) (4) (b) (4)	26 Aug 2020 18:14:42

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered '0'	Crystal Rowell (b) (4)	26 Aug 2020 18:14:42

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered '99'	Crystal Rowell (b) (4)	26 Aug 2020 18:14:42

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User entered '%'	System	26 Aug 2020 18:14:42

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered '37.5' C	Crystal Rowell (b) (4)	26 Aug 2020 18:14:42

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User entered 'None (None)'	Crystal Rowell (b) (4)	26 Aug 2020 18:14:42

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User entered 'Mild (Mild)'	Crystal Rowell (b) (4)	26 Aug 2020 18:14:42

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 20:56:05
	Crystal Rowell (b) (4)	26 Aug 2020 18:14:42
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	26 Aug 2020 18:14:42
	Crystal Rowell (b) (4)	
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'Moderate (Moderate)'	Crystal Rowell (b) (4)	26 Aug 2020 18:14:42

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User entered 'Mild (Mild)'	(b) (4), (b) (6)	04 Nov 2020 20:56:05
	Crystal Rowell (b) (4)	26 Aug 2020 18:14:42
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'Mild (Mild)'	Crystal Rowell (b) (4)	26 Aug 2020 18:14:42
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	26 Aug 2020 18:14:42
	Crystal Rowell (b) (4)	
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User entered 'None (None)'	Crystal Rowell (b) (4)	26 Aug 2020 18:14:42

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	Crystal Rowell (b) (4)	26 Aug 2020 18:14:42

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'Mild (Mild)'	Crystal Rowell (b) (4)	26 Aug 2020 18:14:42
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 20:56:05
	Crystal Rowell (b) (4)	26 Aug 2020 18:14:42
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	Crystal Rowell (b) (4)	26 Aug 2020 18:14:42

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	Crystal Rowell (b) (4)	26 Aug 2020 18:14:42
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	Crystal Rowell (b) (4)	26 Aug 2020 18:14:42

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'Mild (Mild)'	Crystal Rowell (b) (4)	26 Aug 2020 18:14:42

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:36:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
User entered 'Day 5 (Day 5)' reason for change:	(b) (4)	
Data Entry Error	Alexandra Caillouet	02 Dec 2020 14:25:20
User entered 'Day 2 (Day 2)'	(b) (4)	
	Crystal Rowell (b) (4)	26 Aug 2020 18:16:15
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:36:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User entered '22 Aug 2020'	Crystal Rowell (b) (4)	26 Aug 2020 18:16:15

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:36:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered '0'	Crystal Rowell (b) (4)	26 Aug 2020 18:16:15

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:36:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered '99'	Crystal Rowell (b) (4)	26 Aug 2020 18:16:15

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:36:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User entered '%'	System	26 Aug 2020 18:16:15

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:36:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User entered '99' F	Crystal Rowell (b) (4)	26 Aug 2020 18:16:15

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:36:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	26 Aug 2020 18:16:15
	Crystal Rowell (b) (4)	
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:36:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User entered 'Mild (Mild)'	Crystal Rowell (b) (4)	26 Aug 2020 18:16:15

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:36:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	Crystal Rowell (b) (4)	26 Aug 2020 18:16:15

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:36:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	Crystal Rowell (b) (4)	26 Aug 2020 18:16:15

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:36:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'Mild (Mild)'	Crystal Rowell (b) (4)	26 Aug 2020 18:16:15

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:36:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 20:56:05
	Crystal Rowell (b) (4)	26 Aug 2020 18:16:15
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:36:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	Crystal Rowell (b) (4)	26 Aug 2020 18:16:15

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:36:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 20:56:05
	Crystal Rowell (b) (4)	26 Aug 2020 18:16:15
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:36:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	26 Aug 2020 18:16:15
	Crystal Rowell (b) (4)	
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:36:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	26 Aug 2020 18:16:15
	Crystal Rowell (b) (4)	
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:36:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'Mild (Mild)'	Crystal Rowell (b) (4)	26 Aug 2020 18:16:15
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:36:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	Crystal Rowell (b) (4)	26 Aug 2020 18:16:15

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:36:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	Crystal Rowell (b) (4)	26 Aug 2020 18:16:15

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:36:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	26 Aug 2020 18:16:15
	Crystal Rowell (b) (4)	
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:36:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	Crystal Rowell (b) (4)	26 Aug 2020 18:16:15

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:36:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User entered 'Mild (Mild)'	(b) (4), (b) (6)	04 Nov 2020 20:56:05
	Crystal Rowell (b) (4)	26 Aug 2020 18:16:15
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:36:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
User entered 'Day 6 (Day 6)' reason for change:	(b) (4)	
Data Entry Error	Alexandra Caillouet	02 Dec 2020 14:25:20
User entered 'Day 3 (Day 3)'	(b) (4)	
	Crystal Rowell (b) (4)	26 Aug 2020 18:17:16
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:36:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User entered '23 Aug 2020'	Crystal Rowell (b) (4)	26 Aug 2020 18:17:16

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:36:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered '0'	Crystal Rowell (b) (4)	26 Aug 2020 18:17:16

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:36:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered '99'	Crystal Rowell (b) (4)	26 Aug 2020 18:17:16

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:36:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User entered '%'	System	26 Aug 2020 18:17:16

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:36:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User entered '99' F	Crystal Rowell (b) (4)	26 Aug 2020 18:17:16

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:36:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	26 Aug 2020 18:17:16
	Crystal Rowell (b) (4)	
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:36:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'Mild (Mild)'	Crystal Rowell (b) (4)	26 Aug 2020 18:17:16

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:36:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	Crystal Rowell (b) (4)	26 Aug 2020 18:17:16

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:36:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	26 Aug 2020 18:17:16
	Crystal Rowell (b) (4)	
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:36:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	26 Aug 2020 18:17:16

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:36:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 20:56:05
	Crystal Rowell (b) (4)	26 Aug 2020 18:17:16
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:36:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	26 Aug 2020 18:17:16
	Crystal Rowell (b) (4)	
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:36:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	26 Aug 2020 18:17:16
	Crystal Rowell (b) (4)	
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:36:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	Crystal Rowell (b) (4)	26 Aug 2020 18:17:16

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:36:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User entered 'None (None)'	Crystal Rowell (b) (4)	26 Aug 2020 18:17:16

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:36:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User entered 'Mild (Mild)'	(b) (4), (b) (6)	04 Nov 2020 20:56:05
	Crystal Rowell (b) (4)	26 Aug 2020 18:17:16
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:36:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User entered 'Mild (Mild)'	Crystal Rowell (b) (4)	26 Aug 2020 18:17:16

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:36:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	26 Aug 2020 18:17:16
	Crystal Rowell (b) (4)	
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:36:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	26 Aug 2020 18:17:16
	Crystal Rowell (b) (4)	
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:36:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User entered 'None (None)'	Crystal Rowell (b) (4)	26 Aug 2020 18:17:16

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:36:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	Crystal Rowell (b) (4)	26 Aug 2020 18:17:16

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:36:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
User entered 'Day 7 (Day 7)' reason for change:	(b) (4)	
Data Entry Error	Alexandra Caillouet	02 Dec 2020 14:25:20
User entered 'Day 4 (Day 4)'	(b) (4)	
	Crystal Rowell (b) (4)	26 Aug 2020 18:18:15
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:36:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User entered '24 Aug 2020'	Crystal Rowell (b) (4)	26 Aug 2020 18:18:15

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:36:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered '0'	Crystal Rowell (b) (4)	26 Aug 2020 18:18:15

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:36:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered '99'	Crystal Rowell (b) (4)	26 Aug 2020 18:18:15

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:36:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User entered '%'	System	26 Aug 2020 18:18:15

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:36:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:56:05
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	26 Aug 2020 18:36:36
User entered '98.6' F reason for change: Data Entry Error	Crystal Rowell (b) (4) (b) (4)	26 Aug 2020 18:36:36
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	26 Aug 2020 18:18:15
User entered '98.6' (non-conformant).	Crystal Rowell (b) (4) (b) (4)	26 Aug 2020 18:18:15

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:36:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	26 Aug 2020 18:18:15
	Crystal Rowell (b) (4)	
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:36:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	26 Aug 2020 18:18:15

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:36:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	Crystal Rowell (b) (4)	26 Aug 2020 18:18:15

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:36:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	26 Aug 2020 18:18:15
	Crystal Rowell (b) (4)	
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:36:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	Crystal Rowell (b) (4)	26 Aug 2020 18:18:15

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:36:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 20:56:05
	Crystal Rowell (b) (4)	26 Aug 2020 18:18:15
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:36:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	Crystal Rowell (b) (4)	26 Aug 2020 18:18:15
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:36:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	26 Aug 2020 18:18:15
	Crystal Rowell (b) (4)	
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:36:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 20:56:05
	Crystal Rowell (b) (4)	26 Aug 2020 18:18:15
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:36:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	Crystal Rowell (b) (4)	26 Aug 2020 18:18:15

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:36:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	Crystal Rowell (b) (4)	26 Aug 2020 18:18:15
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:36:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 20:56:05
	Crystal Rowell (b) (4)	26 Aug 2020 18:18:15
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:36:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	Crystal Rowell (b) (4)	26 Aug 2020 18:18:15

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:36:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	26 Aug 2020 18:18:15
	Crystal Rowell (b) (4)	
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:36:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	26 Aug 2020 18:18:15
	Crystal Rowell (b) (4)	
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:36:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 20:56:05
	Crystal Rowell (b) (4)	26 Aug 2020 18:18:15
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:36:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
User entered 'Day 8 (Day 8)' reason for change:	(b) (4)	
Data Entry Error	Alexandra Caillouet	02 Dec 2020 14:25:20
User entered 'Day 5 (Day 5)'	(b) (4)	
	Crystal Rowell (b) (4)	26 Aug 2020 18:38:01
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:36:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered '25 Aug 2020'	Crystal Rowell (b) (4)	26 Aug 2020 18:38:01

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:36:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered '0'	Crystal Rowell (b) (4)	26 Aug 2020 18:38:01

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:36:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered '99'	Crystal Rowell (b) (4)	26 Aug 2020 18:38:01

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:36:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User entered '%'	System	26 Aug 2020 18:38:01

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:36:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered '98.7' F reason for change: Data Entry Error	Crystal Rowell (b) (4)	04 Nov 2020 20:50:03
User entered '98.2' F	(b) (4)	
	Crystal Rowell (b) (4)	26 Aug 2020 18:38:01
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:36:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	Crystal Rowell (b) (4)	26 Aug 2020 18:38:01
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:36:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	26 Aug 2020 18:38:01
	Crystal Rowell (b) (4)	
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:36:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	Crystal Rowell (b) (4)	26 Aug 2020 18:38:01

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:36:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	26 Aug 2020 18:38:01
	Crystal Rowell (b) (4)	
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:36:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	Crystal Rowell (b) (4)	26 Aug 2020 18:38:01

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:36:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 20:56:05
	Crystal Rowell (b) (4)	26 Aug 2020 18:38:01
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:36:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	26 Aug 2020 18:38:01
	Crystal Rowell (b) (4)	
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:36:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	26 Aug 2020 18:38:01

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:36:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	Crystal Rowell (b) (4)	26 Aug 2020 18:38:01

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:36:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	Crystal Rowell (b) (4)	26 Aug 2020 18:38:01

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:36:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	Crystal Rowell (b) (4)	26 Aug 2020 18:38:01

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:36:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 20:56:05
	Crystal Rowell (b) (4)	26 Aug 2020 18:38:01
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:36:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	Crystal Rowell (b) (4)	26 Aug 2020 18:38:01

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:36:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	26 Aug 2020 18:38:01
	Crystal Rowell (b) (4)	
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:36:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	Crystal Rowell (b) (4)	26 Aug 2020 18:38:01

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:36:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	Crystal Rowell (b) (4)	26 Aug 2020 18:38:01

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:36:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
User entered 'Day 9 (Day 9)' reason for change:	(b) (4)	
Data Entry Error	Alexandra Caillouet	02 Dec 2020 14:25:20
User entered 'Day 6 (Day 6)'	(b) (4)	
	Crystal Rowell (b) (4)	27 Aug 2020 16:39:41
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:36:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered '26 Aug 2020'	Crystal Rowell (b) (4)	27 Aug 2020 16:39:41

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:36:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered '0'	Crystal Rowell (b) (4)	27 Aug 2020 16:39:41

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:36:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered '99'	Crystal Rowell (b) (4)	27 Aug 2020 16:39:41

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:36:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User entered '%'	System	27 Aug 2020 16:39:41

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:36:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User entered '98.1' F	(b) (4), (b) (6)	04 Nov 2020 20:56:05
	Crystal Rowell (b) (4)	27 Aug 2020 16:39:41
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:36:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	Crystal Rowell (b) (4)	27 Aug 2020 16:39:41

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:36:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	Crystal Rowell (b) (4)	27 Aug 2020 16:39:41
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:36:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	Crystal Rowell (b) (4)	27 Aug 2020 16:39:41

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:36:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	27 Aug 2020 16:39:41
	Crystal Rowell (b) (4)	
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:36:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	Crystal Rowell (b) (4)	27 Aug 2020 16:39:41

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:36:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 20:56:05
	Crystal Rowell (b) (4)	27 Aug 2020 16:39:41
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:36:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	Crystal Rowell (b) (4)	27 Aug 2020 16:39:41

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:36:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	27 Aug 2020 16:39:41
	Crystal Rowell (b) (4)	
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:36:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	Crystal Rowell (b) (4)	27 Aug 2020 16:39:41

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:36:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	Crystal Rowell (b) (4)	27 Aug 2020 16:39:41

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:36:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	Crystal Rowell (b) (4)	27 Aug 2020 16:39:41
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:36:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User entered 'None (None)'	Crystal Rowell (b) (4)	27 Aug 2020 16:39:41

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:36:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	27 Aug 2020 16:39:41
	Crystal Rowell (b) (4)	
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:36:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	27 Aug 2020 16:39:41
	Crystal Rowell (b) (4)	
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:36:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	Crystal Rowell (b) (4)	27 Aug 2020 16:39:41

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:36:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	Crystal Rowell (b) (4)	27 Aug 2020 16:39:41

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:36:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
User entered 'Day 10 (Day 10)' reason for change:	(b) (4)	
Data Entry Error	Alexandra Caillouet	02 Dec 2020 14:25:20
User entered 'Day 7 (Day 7)'	(b) (4)	
	(b) (4), (b) (6)	03 Sep 2020 17:39:04

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:36:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered '27 Aug 2020'	(b) (4), (b) (6)	03 Sep 2020 17:39:04

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:36:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 17:39:04

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:36:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered '99'	(b) (4), (b) (6)	03 Sep 2020 17:39:04

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:36:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User entered '%'	System	03 Sep 2020 17:39:04

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:36:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered '98.5' F	(b) (4), (b) (6)	03 Sep 2020 17:39:04

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:36:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:39:04

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:36:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:39:04

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:36:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:39:04

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:36:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:39:04

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:36:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:39:04

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:36:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:39:04

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:36:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:39:04

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:36:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:39:04

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:36:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:39:04

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:36:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:39:04

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:36:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:39:04

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:36:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:39:04

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:36:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:39:04

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:36:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:39:04

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:36:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:39:04

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:36:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:39:04

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:36:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
User entered 'Day 11 (Day 11)' reason for change:	(b) (4)	
Data Entry Error	Alexandra Caillouet	02 Dec 2020 14:25:20
User entered 'Day 8 (Day 8)'	(b) (4)	
	(b) (4), (b) (6)	03 Sep 2020 17:40:17

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:36:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered '28 Aug 2020'	(b) (4), (b) (6)	03 Sep 2020 17:40:17

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:36:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 17:40:17

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:36:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered '99'	(b) (4), (b) (6)	03 Sep 2020 17:40:17

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:36:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User entered '%'	System	03 Sep 2020 17:40:17

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:36:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered '98.5' F reason for change: Data Entry Error	Crystal Rowell (b) (4)	04 Nov 2020 20:50:38
User entered '98.2' F	(b) (4)	
	(b) (4), (b) (6)	03 Sep 2020 17:40:17

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:36:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:40:17

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:36:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:40:17

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:36:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:40:17

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:36:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:40:17

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:36:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:40:17

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:36:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:40:17

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:36:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:40:17

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:36:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:40:17

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:36:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:40:17

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:36:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:40:17

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:36:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:40:17

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:36:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:40:17

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:36:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:40:17

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:36:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:40:17

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:36:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:40:17

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:36:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:40:17

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:36:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
User entered 'Day 12 (Day 12)' reason for change:	(b) (4)	
Data Entry Error	Alexandra Caillouet	02 Dec 2020 14:25:20
User entered 'Day 9 (Day 9)'	(b) (4)	
	(b) (4), (b) (6)	03 Sep 2020 17:43:03

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:36:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered '29 Aug 2020'	(b) (4), (b) (6)	03 Sep 2020 17:43:03

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:36:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 17:43:03

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:36:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered '99'	(b) (4), (b) (6)	03 Sep 2020 17:43:03

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:36:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User entered '%'	System	03 Sep 2020 17:43:03

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:36:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered '98.2' F	(b) (4), (b) (6)	03 Sep 2020 17:43:03

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:36:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:43:03

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:36:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:43:03

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:36:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:43:03

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:36:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:43:03

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:36:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:43:03

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:36:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:43:03

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:36:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:43:03

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:36:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:43:03

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:36:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:43:03

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:36:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:43:03

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:36:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:43:03

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:36:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:43:03

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:36:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:43:03

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:36:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:43:03

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:36:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:43:03

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:36:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:43:03

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:36:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
User entered 'Day 13 (Day 13)' reason for change:	(b) (4)	
Data Entry Error	Alexandra Caillouet	02 Dec 2020 14:25:20
User entered 'Day 10 (Day 10)' reason for change:	(b) (4)	
Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 17:45:39
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 17:44:13

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:36:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	03 Sep 2020 17:45:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 17:45:08
User entered '30 Aug 2020' reason for change: Data Entry Error	System	03 Sep 2020 17:45:08
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	03 Sep 2020 17:44:13
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 17:44:13

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:36:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 17:44:13

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:36:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered '99'	(b) (4), (b) (6)	03 Sep 2020 17:44:13

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:36:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User entered '%'	System	03 Sep 2020 17:44:13

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:36:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered '98.2' F reason for change: Data Entry Error	Crystal Rowell (b) (4)	04 Nov 2020 20:51:19
User entered '98.1' F	(b) (4)	
	(b) (4), (b) (6)	03 Sep 2020 17:44:13

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:36:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:44:13

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:36:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:44:13

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:36:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:44:13

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:36:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:44:13

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:36:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:44:13

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:36:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:44:13

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:36:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:44:13

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:36:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:44:13

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:36:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:44:13

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:36:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:44:13

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:36:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:44:13

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:36:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:44:13

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:36:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:44:13

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:36:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:44:13

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:36:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:44:13

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:36:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:44:13

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:36:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
User entered 'Day 14 (Day 14)' reason for change:	(b) (4)	
Data Entry Error	Alexandra Caillouet	02 Dec 2020 14:25:45
User entered 'Day 11 (Day 11)'	(b) (4)	
	(b) (4), (b) (6)	03 Sep 2020 17:48:10

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:36:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered '31 Aug 2020'	(b) (4), (b) (6)	03 Sep 2020 17:48:10

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:36:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 17:48:10

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:36:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered '99'	(b) (4), (b) (6)	03 Sep 2020 17:48:10

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:36:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User entered '%'	System	03 Sep 2020 17:48:10

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:36:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered '98.1' F	(b) (4), (b) (6)	03 Sep 2020 17:48:10

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:36:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:48:10

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:36:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:48:10

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:36:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:48:10

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:36:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:48:10

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:36:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:48:10

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:36:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:48:10

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:36:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:48:10

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:36:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:48:10

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:36:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:48:10

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:36:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:48:10

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:36:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:48:10

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:36:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:48:10

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:36:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:48:10

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:36:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:48:10

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:36:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:48:10

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:36:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:48:10

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:36:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
User entered 'Day 15 (Day 15)' reason for change:	(b) (4)	
Data Entry Error	Alexandra Caillouet	02 Dec 2020 14:25:45
User entered 'Day 12 (Day 12)'	(b) (4)	
	(b) (4), (b) (6)	03 Sep 2020 17:48:10

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:36:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered '01 Sep 2020'	(b) (4), (b) (6)	03 Sep 2020 17:48:10

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:36:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 17:48:10

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:36:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered '99'	(b) (4), (b) (6)	03 Sep 2020 17:48:10

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:36:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User entered '%'	System	03 Sep 2020 17:48:10

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:36:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered '97' F	(b) (4), (b) (6)	03 Sep 2020 17:48:10

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:36:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:48:10

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:36:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:48:10

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:36:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:48:10

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:36:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:48:10

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:36:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:48:10

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:36:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:48:10

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:36:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:48:10

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:36:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:48:10

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:36:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:48:10

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:36:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:48:10

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:36:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:48:10

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:36:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:48:10

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:36:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:48:10

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:36:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:48:10

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:36:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:48:10

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:36:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:48:10

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:36:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
User entered 'Day 16 (Day 16)' reason for change:	(b) (4)	
Data Entry Error	Alexandra Caillouet	02 Dec 2020 14:25:45
User entered 'Day 13 (Day 13)'	(b) (4)	
	(b) (4), (b) (6)	03 Sep 2020 17:54:05

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:36:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered '02 Sep 2020'	(b) (4), (b) (6)	03 Sep 2020 17:54:05

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:36:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 17:54:05

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:36:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered '99'	(b) (4), (b) (6)	03 Sep 2020 17:54:05

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:36:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User entered '%'	System	03 Sep 2020 17:54:05

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:36:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered '97.6' F reason for change: Data Entry Error		03 Sep 2020 18:02:36
User entered empty.		03 Sep 2020 17:54:05

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:36:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:54:05

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:36:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:54:05

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:36:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:54:05

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:36:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:54:05

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:36:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:54:05

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:36:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:54:05

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:36:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:54:05

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:36:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:54:05

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:36:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:54:05

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:36:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:54:05

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:36:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:54:05

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:36:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:54:05

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:36:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:54:05

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:36:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:54:05

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:36:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:54:05

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:36:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 17:54:05

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:36:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
User entered 'Day 17 (Day 17)' reason for change:	(b) (4)	
Data Entry Error	Alexandra Caillouet	02 Dec 2020 14:25:45
User entered 'Day 14 (Day 14)'	(b) (4)	
	(b) (4), (b) (6)	03 Sep 2020 18:02:36

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:36:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
User closed query 'Per CDM: it appears there may be additional symptoms not recorded as there is a Convalescence Visit Day 28 with date of 18SEP020. Please reconcile or clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:20:40
Query 'Per CDM: it appears there may be additional symptoms not recorded as there is a Convalescence Visit Day 28 with date of 18SEP020. Please reconcile or clarify.' answered with 'Day 28 symptoms to be added.' (Site from DM).	Alexandra Caillouet (b) (4)	09 Nov 2020 18:32:55
User opened query 'Per CDM: it appears there may be additional symptoms not recorded as there is a Convalescence Visit Day 28 with date of 18SEP020. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 03:46:12
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered '03 Sep 2020'	(b) (4), (b) (6)	03 Sep 2020 18:02:36

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:36:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 18:02:36

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:36:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered '99'	(b) (4), (b) (6)	03 Sep 2020 18:02:36

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:36:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User entered '%'	System	03 Sep 2020 18:02:36

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:36:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:05
User entered '97.4' F	(b) (4), (b) (6)	03 Sep 2020 18:02:36

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:36:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 18:02:36

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:36:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 18:02:36

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:36:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 18:02:36

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:36:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 18:02:36

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:36:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 18:02:36

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:36:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 18:02:36

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:36:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 18:02:36

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:36:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 18:02:36

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:36:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 18:02:36

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:36:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 18:02:36

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:36:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 18:02:36

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:36:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 18:02:36

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:36:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 18:02:36

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:36:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 18:02:36

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:36:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 18:02:36

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:36:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:05
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 18:02:36

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:36:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
User entered 'Day 28 (Day 28)'	Alexandra Caillouet (b) (4)	09 Nov 2020 18:34:38

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:36:21

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
User closed query 'Per CDM re-query: Thank you for your long explanation. However, please be aware that Day 17 was 03Sep2020 and here Day 28 is entered as 18Sep2020, however when counting days then Day 28 should be 14Sep2020 instead of 18Sep2020. Please review and update or clarify otherwise. Thank you!' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 17:29:33
Query 'Per CDM re-query: Thank you for your long explanation. However, please be aware that Day 17 was 03Sep2020 and here Day 28 is entered as 18Sep2020, however when counting days then Day 28 should be 14Sep2020 instead of 18Sep2020. Please review and update or clarify otherwise. Thank you!' answered with 'Subject was unable to come on this date and was scheduled out of the original illness window of 14Sep2020 which was suppose to be Day 28 for them. However they were scheduled on 18Sep2020 and PD log has been updated as well. ' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 14:37:10
User opened query 'Per CDM re-query: Thank you for your long explanation. However, please be aware that Day 17 was 03Sep2020 and here Day 28 is entered as 18Sep2020, however when counting days then Day 28 should be 14Sep2020 instead of 18Sep2020. Please review and update or clarify otherwise. Thank you!' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 08:26:19
User closed query 'Per CDM: Please confirm this date, because Day 17 is 03Sep2020, however here it is entered that Day 28 is 18Sep2020. Also, please be aware that "Covid-19 Assessment 18Sep2020" folder has a Symptom log with a date 18Sep2020. Please review all these dates and update or clarify otherwise. Thank you!' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 08:26:19

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:36:21

[Date](#)

Audit	User	Time (GMT)
Query 'Per CDM: Please confirm this date, because Day 17 is 03Sep2020, however here it is entered that Day 28 is 18Sep2020. Also, please be aware that "Covid-19 Assessment 18Sep2020" folder has a Symptom log with a date 18Sep2020. Please review all these dates and update or clarify otherwise. Thank you!' answered with 'Subject came in for Illness day 1 on 21AUG2020. Subject was followed daily up until day 17 on 03SEP2020. Since subjects NP swab from Illness day 1 was positive, subject needed to complete illness day 2, Day 28 visit. Day 28 visit occurred on 18SEP2020. At that visit, another illness Day 1 kit was used accidentally, and therefore another NP swab was done. Previous query had requested that the swab from that visit be captured in EDC by opening another COVID-19 assessment and that is why there is another assessment entered for 18SEP2020 with the symptom log only indicating the Day28. ' (Site from DM).	Alexandra Caillouet (b) (4)	22 Mar 2021 18:59:11
User opened query 'Per CDM: Please confirm this date, because Day 17 is 03Sep2020, however here it is entered that Day 28 is 18Sep2020. Also, please be aware that "Covid-19 Assessment 18Sep2020" folder has a Symptom log with a date 18Sep2020. Please review all these dates and update or clarify otherwise. Thank you!' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 12:34:03
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:27
User entered '18 Sep 2020'	Alexandra Caillouet (b) (4)	09 Nov 2020 18:34:38

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:36:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:03:57
User closed query 'Per CDM: It appears Assessment Not Done is checked yet data is present. Please reconcile' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 11:56:34
Query 'Per CDM: It appears Assessment Not Done is checked yet data is present. Please reconcile' answered with 'update' (Site from DM).	Alexandra Caillouet (b) (4)	08 Jan 2021 22:00:25
DataPoint Un-verified.	Alexandra Caillouet (b) (4)	08 Jan 2021 22:00:19
User entered '0' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	08 Jan 2021 22:00:19
User opened query 'Per CDM: It appears Assessment Not Done is checked yet data is present. Please reconcile' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 10:50:04
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:27
User entered '1'	Alexandra Caillouet (b) (4)	09 Nov 2020 18:34:38

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:36:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:27
User entered '99'	Alexandra Caillouet (b) (4)	09 Nov 2020 18:34:38

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:36:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User entered '%'	System	09 Nov 2020 18:34:38

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:36:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:54:27
User entered '37.1' C	Alexandra Caillouet	09 Nov 2020 18:34:38
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:36:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:54:27
User entered 'None (None)'	Alexandra Caillouet	09 Nov 2020 18:34:38
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:36:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:54:27
User entered 'None (None)'	Alexandra Caillouet	09 Nov 2020 18:34:38
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:36:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:54:27
User entered 'None (None)'	Alexandra Caillouet	09 Nov 2020 18:34:38
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:36:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:54:27
User entered 'None (None)'	Alexandra Caillouet	09 Nov 2020 18:34:38
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:36:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:54:27
User entered 'None (None)'	Alexandra Caillouet	09 Nov 2020 18:34:38
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:36:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:54:27
User entered 'None (None)'	Alexandra Caillouet	09 Nov 2020 18:34:38
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:36:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:54:27
User entered 'None (None)'	Alexandra Caillouet	09 Nov 2020 18:34:38
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:36:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:54:27
User entered 'None (None)'	Alexandra Caillouet	09 Nov 2020 18:34:38
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:36:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:27
User entered 'None (None)'	Alexandra Caillouet (b) (4)	09 Nov 2020 18:34:38

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:36:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:54:27
User entered 'None (None)'	Alexandra Caillouet	09 Nov 2020 18:34:38
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:36:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:54:27
User entered 'None (None)'	Alexandra Caillouet	09 Nov 2020 18:34:38
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:36:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:54:27
User entered 'None (None)'	Alexandra Caillouet	09 Nov 2020 18:34:38
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:36:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:54:27
User entered 'None (None)'	Alexandra Caillouet	09 Nov 2020 18:34:38
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:36:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:54:27
User entered 'None (None)'	Alexandra Caillouet	09 Nov 2020 18:34:38
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:36:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:54:27
User entered 'None (None)'	Alexandra Caillouet	09 Nov 2020 18:34:38
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:36:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:27
User entered 'None (None)'	Alexandra Caillouet (b) (4)	09 Nov 2020 18:34:38

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:36:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
User entered 'Day 3 (Day 3)'	Alexandra Caillouet (b) (4)	02 Dec 2020 14:24:32

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:36:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:03:57
User entered '20 Aug 2020'	Alexandra Caillouet (b) (4)	02 Dec 2020 14:24:32

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:36:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:03:57
User closed query 'Per CDM: It appears Assessment Not Done is checked yet data is present. Please reconcile' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 11:56:41
Query 'Per CDM: It appears Assessment Not Done is checked yet data is present. Please reconcile' answered with 'updated' (Site from DM).	Alexandra Caillouet (b) (4)	08 Jan 2021 22:01:41
User opened query 'Per CDM: It appears Assessment Not Done is checked yet data is present. Please reconcile' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 10:50:28
User entered 'I'	Alexandra Caillouet (b) (4)	02 Dec 2020 14:24:32

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:36:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:03:57
User entered empty.	Alexandra Caillouet (b) (4)	02 Dec 2020 14:24:32

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:36:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User entered empty.	System	02 Dec 2020 14:24:32

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:36:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:03:57
User entered empty.	Alexandra Caillouet (b) (4)	02 Dec 2020 14:24:32

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:36:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:03:57
User entered empty; reason for change Data Entry Error	Alexandra Caillouet	08 Jan 2021 22:01:35
	(b) (4)	
User entered 'Not Done (Not Done)'	Alexandra Caillouet	02 Dec 2020 14:24:32
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:36:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:03:57
User entered empty; reason for change Data Entry Error	Alexandra Caillouet	08 Jan 2021 22:01:35
	(b) (4)	
User entered 'Not Done (Not Done)'	Alexandra Caillouet	02 Dec 2020 14:24:32
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:36:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	12 Apr 2021 19:03:57
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	
User entered 'Not Done (Not Done)'	Alexandra Caillouet	08 Jan 2021 22:01:35
	(b) (4)	
	Alexandra Caillouet	02 Dec 2020 14:24:32
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:36:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:03:57
User entered empty; reason for change Data Entry Error	Alexandra Caillouet (b) (4)	08 Jan 2021 22:01:35
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	02 Dec 2020 14:24:32

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:36:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	12 Apr 2021 19:03:57
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	
User entered 'Not Done (Not Done)'	Alexandra Caillouet	08 Jan 2021 22:01:35
	(b) (4)	
	Alexandra Caillouet	02 Dec 2020 14:24:32
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:36:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:03:57
User entered empty; reason for change Data Entry Error	Alexandra Caillouet (b) (4)	08 Jan 2021 22:01:35
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	02 Dec 2020 14:24:32

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:36:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:03:57
User entered empty; reason for change Data Entry Error	Alexandra Caillouet (b) (4)	08 Jan 2021 22:01:35
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	02 Dec 2020 14:24:32

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:36:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:03:57
User entered empty; reason for change Data Entry Error	Alexandra Caillouet	08 Jan 2021 22:01:35
	(b) (4)	
User entered 'Not Done (Not Done)'	Alexandra Caillouet	02 Dec 2020 14:24:32
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:36:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	12 Apr 2021 19:03:57
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	
	Alexandra Caillouet	08 Jan 2021 22:01:35
User entered 'Not Done (Not Done)'	(b) (4)	
	Alexandra Caillouet	02 Dec 2020 14:24:32
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:36:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:03:57
User entered empty; reason for change Data Entry Error	Alexandra Caillouet (b) (4)	08 Jan 2021 22:01:35
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	02 Dec 2020 14:24:32

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:36:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	12 Apr 2021 19:03:57
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	
	Alexandra Caillouet	08 Jan 2021 22:01:35
User entered 'Not Done (Not Done)'	(b) (4)	
	Alexandra Caillouet	02 Dec 2020 14:24:32
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:36:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:03:57
User entered empty; reason for change Data Entry Error	Alexandra Caillouet (b) (4)	08 Jan 2021 22:01:35
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	02 Dec 2020 14:24:32

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:36:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	12 Apr 2021 19:03:57
User entered empty; reason for change Data Entry Error	Alexandra Caillouet	08 Jan 2021 22:01:35
User entered 'Not Done (Not Done)'	(b) (4)	02 Dec 2020 14:24:32

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:36:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:03:57
User entered empty; reason for change Data Entry Error	Alexandra Caillouet	08 Jan 2021 22:01:35
	(b) (4)	
User entered 'Not Done (Not Done)'	Alexandra Caillouet	02 Dec 2020 14:24:32
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:36:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:03:57
User entered empty; reason for change Data Entry Error	Alexandra Caillouet (b) (4)	08 Jan 2021 22:01:35
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	02 Dec 2020 14:24:32

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:36:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:03:57
User entered empty; reason for change Data Entry Error	Alexandra Caillouet (b) (4)	08 Jan 2021 22:01:35
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	02 Dec 2020 14:24:32

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:36:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
User entered 'Day 2 (Day 2)'	Alexandra Caillouet (b) (4)	02 Dec 2020 14:24:32

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:36:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:03:57
User entered '19 Aug 2020'	Alexandra Caillouet (b) (4)	02 Dec 2020 14:24:32

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:36:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:03:57
User closed query 'Per CDM: It appears Assessment Not Done is checked yet data is present. Please reconcile' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 11:56:46
Query 'Per CDM: It appears Assessment Not Done is checked yet data is present. Please reconcile' answered with 'updated' (Site from DM).	Alexandra Caillouet (b) (4)	08 Jan 2021 22:16:44
User opened query 'Per CDM: It appears Assessment Not Done is checked yet data is present. Please reconcile' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 10:51:07
User entered 'I'	Alexandra Caillouet (b) (4)	02 Dec 2020 14:24:32

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:36:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:03:57
User entered empty.	Alexandra Caillouet (b) (4)	02 Dec 2020 14:24:32

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:36:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User entered empty.	System	02 Dec 2020 14:24:32

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:36:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:03:57
User entered empty.	Alexandra Caillouet (b) (4)	02 Dec 2020 14:24:32

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:36:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:03:57
User entered empty; reason for change Data Entry Error	Alexandra Caillouet (b) (4)	08 Jan 2021 22:15:19
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	02 Dec 2020 14:24:32

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:36:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:03:57
User entered empty; reason for change Data Entry Error	Alexandra Caillouet (b) (4)	08 Jan 2021 22:15:19
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	02 Dec 2020 14:24:32

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:36:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:03:57
User entered empty; reason for change Data Entry Error	Alexandra Caillouet	08 Jan 2021 22:15:19
	(b) (4)	
User entered 'Not Done (Not Done)'	Alexandra Caillouet	02 Dec 2020 14:24:32
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:36:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:03:57
User entered empty; reason for change Data Entry Error	Alexandra Caillouet (b) (4)	08 Jan 2021 22:15:19
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	02 Dec 2020 14:24:32

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:36:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	12 Apr 2021 19:03:57
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	
User entered 'Not Done (Not Done)'	Alexandra Caillouet	08 Jan 2021 22:15:19
	(b) (4)	
	Alexandra Caillouet	02 Dec 2020 14:24:32
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:36:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:03:57
User entered empty; reason for change Data Entry Error	Alexandra Caillouet (b) (4)	08 Jan 2021 22:15:19
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	02 Dec 2020 14:24:32

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:36:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:03:57
User entered empty; reason for change Data Entry Error	Alexandra Caillouet (b) (4)	08 Jan 2021 22:15:19
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	02 Dec 2020 14:24:32

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:36:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:03:57
User entered empty; reason for change Data Entry Error	Alexandra Caillouet (b) (4)	08 Jan 2021 22:15:19
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	02 Dec 2020 14:24:32

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:36:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	12 Apr 2021 19:03:57
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	
User entered 'Not Done (Not Done)'	Alexandra Caillouet	08 Jan 2021 22:15:19
	(b) (4)	
	Alexandra Caillouet	02 Dec 2020 14:24:32
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:36:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	12 Apr 2021 19:03:57
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	
	Alexandra Caillouet	08 Jan 2021 22:15:19
User entered 'Not Done (Not Done)'	(b) (4)	
	Alexandra Caillouet	02 Dec 2020 14:24:32
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:36:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	12 Apr 2021 19:03:57
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	
	Alexandra Caillouet	08 Jan 2021 22:15:19
User entered 'Not Done (Not Done)'	(b) (4)	
	Alexandra Caillouet	02 Dec 2020 14:24:32
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:36:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	12 Apr 2021 19:03:57
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	
User entered 'Not Done (Not Done)'	Alexandra Caillouet	08 Jan 2021 22:15:19
	(b) (4)	
	Alexandra Caillouet	02 Dec 2020 14:24:32
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:36:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:03:57
User entered empty; reason for change Data Entry Error	Alexandra Caillouet (b) (4)	08 Jan 2021 22:15:19
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	02 Dec 2020 14:24:32

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:36:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:03:57
User entered empty; reason for change Data Entry Error	Alexandra Caillouet (b) (4)	08 Jan 2021 22:15:19
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	02 Dec 2020 14:24:32

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:36:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:03:57
User entered empty; reason for change Data Entry Error	Alexandra Caillouet (b) (4)	08 Jan 2021 22:15:19
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	02 Dec 2020 14:24:32

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:36:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:03:57
User entered empty; reason for change Data Entry Error	Alexandra Caillouet (b) (4)	08 Jan 2021 22:15:19
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	02 Dec 2020 14:24:32

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:36:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
User entered 'Day 1 (Day 1)'	Alexandra Caillouet (b) (4)	02 Dec 2020 14:24:32

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:36:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:03:57
User entered '18 Aug 2020'	Alexandra Caillouet (b) (4)	02 Dec 2020 14:24:32

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:36:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:03:57
User closed query 'Per CDM: It appears Assessment Not Done is checked yet data is present. Please reconcile' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 11:56:51
Query 'Per CDM: It appears Assessment Not Done is checked yet data is present. Please reconcile' answered with 'updated' (Site from DM).	Alexandra Caillouet (b) (4)	08 Jan 2021 22:16:33
User opened query 'Per CDM: It appears Assessment Not Done is checked yet data is present. Please reconcile' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 10:51:17
User entered 'I'	Alexandra Caillouet (b) (4)	02 Dec 2020 14:24:32

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:36:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:03:57
User entered empty.	Alexandra Caillouet (b) (4)	02 Dec 2020 14:24:32

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:36:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User entered empty.	System	02 Dec 2020 14:24:32

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:36:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:03:57
User entered empty.	Alexandra Caillouet (b) (4)	02 Dec 2020 14:24:32

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:36:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:03:57
User entered empty; reason for change Data Entry Error	Alexandra Caillouet (b) (4)	08 Jan 2021 22:16:20
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	02 Dec 2020 14:24:32

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:36:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:03:57
User entered empty; reason for change Data Entry Error	Alexandra Caillouet (b) (4)	08 Jan 2021 22:16:20
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	02 Dec 2020 14:24:32

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:36:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	12 Apr 2021 19:03:57
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	
User entered 'Not Done (Not Done)'	Alexandra Caillouet	08 Jan 2021 22:16:20
	(b) (4)	
	Alexandra Caillouet	02 Dec 2020 14:24:32
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:36:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:03:57
User entered empty; reason for change Data Entry Error	Alexandra Caillouet (b) (4)	08 Jan 2021 22:16:20
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	02 Dec 2020 14:24:32

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:36:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:03:57
User entered empty; reason for change Data Entry Error	Alexandra Caillouet (b) (4)	08 Jan 2021 22:16:20
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	02 Dec 2020 14:24:32

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:36:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:03:57
User entered empty; reason for change Data Entry Error	Alexandra Caillouet (b) (4)	08 Jan 2021 22:16:20
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	02 Dec 2020 14:24:32

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:36:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:03:57
User entered empty; reason for change Data Entry Error	Alexandra Caillouet (b) (4)	08 Jan 2021 22:16:20
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	02 Dec 2020 14:24:32

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:36:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:03:57
User entered empty; reason for change Data Entry Error	Alexandra Caillouet (b) (4)	08 Jan 2021 22:16:20
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	02 Dec 2020 14:24:32

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:36:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:03:57
User entered empty; reason for change Data Entry Error	Alexandra Caillouet (b) (4)	08 Jan 2021 22:16:20
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	02 Dec 2020 14:24:32

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:36:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	12 Apr 2021 19:03:57
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	
User entered 'Not Done (Not Done)'	Alexandra Caillouet	08 Jan 2021 22:16:20
	(b) (4)	
	Alexandra Caillouet	02 Dec 2020 14:24:32
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:36:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:03:57
User entered empty; reason for change Data Entry Error	Alexandra Caillouet (b) (4)	08 Jan 2021 22:16:20
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	02 Dec 2020 14:24:32

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:36:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:03:57
User entered empty; reason for change Data Entry Error	Alexandra Caillouet (b) (4)	08 Jan 2021 22:16:20
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	02 Dec 2020 14:24:32

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:36:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:03:57
User entered empty; reason for change Data Entry Error	Alexandra Caillouet (b) (4)	08 Jan 2021 22:16:20
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	02 Dec 2020 14:24:32

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:36:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:03:57
User entered empty; reason for change Data Entry Error	Alexandra Caillouet (b) (4)	08 Jan 2021 22:16:20
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	02 Dec 2020 14:24:32

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:36:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:03:57
User entered empty; reason for change Data Entry Error	Alexandra Caillouet (b) (4)	08 Jan 2021 22:16:20
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	02 Dec 2020 14:24:32

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:36:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:03:57
User entered empty; reason for change Data Entry Error	Alexandra Caillouet (b) (4)	08 Jan 2021 22:16:20
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	02 Dec 2020 14:24:32

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:36:21

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:51:03
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 18-SEP-2020 is reported under Illness Visit Day 1 in PPD portal; however, swab sample for 18-SEP-2020 is missing in EDC. Kindly confirm if swab sample was collected if yes, please update by initiating Covid -19 Assessment eCRF for the corresponding date and updating swab data in the COVID Diagnostic Test eCRF, else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Jan 2021 16:27:18
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 18-SEP-2020 is reported under Illness Visit Day 1 in PPD portal; however, swab sample for 18-SEP-2020 is missing in EDC. Kindly confirm if swab sample was collected if yes, please update by initiating Covid -19 Assessment eCRF for the corresponding date and updating swab data in the COVID Diagnostic Test eCRF, else clarify.'	Amy Thomassie (b) (4) (b) (4)	30 Dec 2020 15:41:14
answered with 'The swab collected on 18-SEP-2020 was for convalescent period day 28. on 24-Nov-2020 a data clarification form was received by PPD and the report was revised to reflect illness day 28. Therefore, there is no need to initiate another Covid-19 assessment eCRF' (Site from DM).		
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 18-SEP-2020 is reported under Illness Visit Day 1 in PPD portal; however, swab sample for 18-SEP-2020 is missing in EDC. Kindly confirm if swab sample was collected if yes, please update by initiating Covid -19 Assessment eCRF for the corresponding date and updating swab data in the COVID Diagnostic Test eCRF, else clarify.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 07:12:55

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:36:21

[Date of Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation requery: Swab: Per site response to previous query," subject was swabbed on 21aug 2020 and 18 sep 2020", however, swab sample for 18 SEP 2020 is missing in EDC. Kindly review if the swab sample for 18 SEP 2020 was collected, if yes, consider updating EDC by initiating new Covid -19 Assessment eCRF for the corresponding date and updating swab data in the COVID Diagnostic form, else clarify.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 11:47:16
Query 'Per GCL Lab Reconciliation requery: Swab: Per site response to previous query," subject was swabbed on 21aug 2020 and 18 sep 2020", however, swab sample for 18 SEP 2020 is missing in EDC. Kindly review if the swab sample for 18 SEP 2020 was collected, if yes, consider updating EDC by initiating new Covid -19 Assessment eCRF for the corresponding date and updating swab data in the COVID Diagnostic form, else clarify.' answered with 'Accession Number: 1F67708' (Site from DM).	Alexandra Caillouet (b) (4)	09 Dec 2020 21:45:38
User opened query 'Per GCL Lab Reconciliation requery: Swab: Per site response to previous query," subject was swabbed on 21aug 2020 and 18 sep 2020", however, swab sample for 18 SEP 2020 is missing in EDC. Kindly review if the swab sample for 18 SEP 2020 was collected, if yes, consider updating EDC by initiating new Covid -19 Assessment eCRF for the corresponding date and updating swab data in the COVID Diagnostic form, else clarify.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 05:59:00
User closed query 'Per GCL Lab Recon Re-query: SWAB: Per response "NP Swab collected instead of Saliva", however there is no data for NP swab in EDC, please verify and update.Thanks.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 06:08:22
Query 'Per GCL Lab Recon Re-query: SWAB: Per response "NP Swab collected instead of Saliva", however there is no data for NP swab in EDC, please verify and update.Thanks.' answered with 'NP swab collected on 21Aug2020, documented under COVID-19 assessments. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 16:47:09

PRODUCTION RELEASE (v12.003
EAB) (1725)

1854 of 2410

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:36:21

[Date of Visit](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Recon Re-query: SWAB: Per response "NP Swab collected instead of Saliva", however there is no data for NP swab in EDC, please verify and update.Thanks.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 10:24:44
User closed query 'Per GCL Lab Recon Re-query: SWAB: Response noted. However Covid Diagnostic Test for sample collected on 18Sep2020 is not yet entered in EDC. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 10:24:44
Query 'Per GCL Lab Recon Re-query: SWAB: Response noted. However Covid Diagnostic Test for sample collected on 18Sep2020 is not yet entered in EDC. Please reconcile.' answered with 'NP swab collected instead of saliva' (Site from DM).	Crystal Rowell (b) (4) (b) (4)	19 Nov 2020 13:00:07
User opened query 'Per GCL Lab Recon Re-query: SWAB: Response noted. However Covid Diagnostic Test for sample collected on 18Sep2020 is not yet entered in EDC. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 12:54:55
User closed query 'Per GCL Lab Recon: GCL has swab samples with dates of 21AUG2020 and 18SEP2020. Please reconcile or clarify' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 12:54:55
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:24
Query 'Per GCL Lab Recon: GCL has swab samples with dates of 21AUG2020 and 18SEP2020. Please reconcile or clarify' answered with 'subject was swabbed on 21aug 2020 and 18 sep 2020' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 21:58:52
User opened query 'Per GCL Lab Recon: GCL has swab samples with dates of 21AUG2020 and 18SEP2020. Please reconcile or clarify' (Site from DM).	(b) (4), (b) (6)	25 Oct 2020 12:34:09
User entered '21 Aug 2020'	Crystal Rowell (b) (4) (b) (4)	27 Aug 2020 16:33:03

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:36:21

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:51:03
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:24
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	27 Aug 2020 16:33:03

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:36:21

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:51:03
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:56:24
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	31 Aug 2020 18:22:07
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'yes' (Site from System).	Crystal Rowell (b) (4) (b) (4)	27 Aug 2020 16:33:13
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	27 Aug 2020 16:33:03
User entered 'Yes (Y)'	Crystal Rowell (b) (4) (b) (4)	27 Aug 2020 16:33:03

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:36:21

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:51:03
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:24
User entered '21 Aug 2020'	Crystal Rowell (b) (4)	27 Aug 2020 16:33:03

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:36:21

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:51:03
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:24
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Crystal Rowell (b) (4)	27 Aug 2020 16:33:03

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:36:21

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:51:03
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:24
User entered empty.	Crystal Rowell (b) (4)	27 Aug 2020 16:33:03

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:36:21

[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)	02 May 2021 07:51:03
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 20:56:24
User entered 'No (N)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	27 Aug 2020 16:33:28
User entered 'Yes (Y)'	(b) (4)	
	Crystal Rowell (b) (4)	27 Aug 2020 16:33:03
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:36:21

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:51:03
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 20:56:24
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	27 Aug 2020 16:33:28
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Aug 2020 16:33:03
User entered empty.	Crystal Rowell (b) (4)	27 Aug 2020 16:33:03
	(b) (4)	

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:36:21

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:51:03
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:56:24
User closed query 'Data is required. Please provide.' (Site from System).	System	27 Aug 2020 16:33:28
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Aug 2020 16:33:03
User entered empty.	Crystal Rowell (b) (4) (b) (4)	27 Aug 2020 16:33:03

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:36:21

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:51:03
User entered 'I'	System	27 Aug 2020 16:33:03

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:36:21

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:51:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:33
User entered 'No (N)'	Crystal Rowell (b) (4)	27 Aug 2020 16:38:14

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:36:21

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:51:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:33
User entered empty.	Crystal Rowell (b) (4)	27 Aug 2020 16:38:14

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:36:21

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:51:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:33
User entered empty.	Crystal Rowell (b) (4)	27 Aug 2020 16:38:14

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:36:21

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:51:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:33
User entered empty.	Crystal Rowell (b) (4)	27 Aug 2020 16:38:14

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:36:21

Did the subject have Heart Rate \geq 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:51:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:33
User entered 'No (N)'	Crystal Rowell (b) (4)	27 Aug 2020 16:38:14

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:36:21

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:51:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:33
User entered empty.	Crystal Rowell (b) (4)	27 Aug 2020 16:38:14

US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:36:21

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:51:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
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US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:36:21

[Heart Rate](#)

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US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:36:21

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)	02 May 2021 07:51:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
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US3362124

Folder: Covid-19 Assessment 21 Aug 2020

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US3362124

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US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:36:21

[Oxygen Saturation](#)

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US3362124

Folder: Covid-19 Assessment 21 Aug 2020

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Generated On: 11 Aug 2021 22:36:21

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

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US3362124

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US3362124

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US3362124

Folder: Covid-19 Assessment 21 Aug 2020

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Generated On: 11 Aug 2021 22:36:21

[PaO2](#)

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US3362124

Folder: Covid-19 Assessment 21 Aug 2020

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Did the subject have Respiratory failure?

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US3362124

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US3362124

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Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:36:21

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

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US3362124

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US3362124

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Generated On: 11 Aug 2021 22:36:21

[High-Flow Oxygen?](#)

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US3362124

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US3362124

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US3362124

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[Non-Invasive Ventilation?](#)

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US3362124

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US3362124

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US3362124

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[Mechanical Ventilation?](#)

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US3362124

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US3362124

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[ECMO?](#)

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US3362124

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[Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg](#)

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US3362124

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[Evidence of Shock Requires](#)

[Vasopressors](#)

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US3362124

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US3362124

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Generated On: 11 Aug 2021 22:36:21

[Acute Renal Dysfunction?](#)

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US3362124

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US3362124

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[Hepatic Dysfunction?](#)

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US3362124

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US3362124

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[Neurologic Dysfunction?](#)

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	(b) (4)	

US3362124

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US3362124

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[Clinical Evidence](#)

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US3362124

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US3362124

Folder: Covid-19 Assessment 21 Aug 2020

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[Radiographical Evidence](#)

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US3362124

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US3362124

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[Admission to an intensive care unit due to SARS-CoV-2](#)

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US3362124

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US3362124

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US3362124

Folder: Covid-19 Assessment 21 Aug 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:36:21

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:51:15
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 20:56:44
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Oct 2020 18:09:24
User entered 'No (N)'	Amy Thomassie (b) (4)	18 Sep 2020 15:42:05
	(b) (4)	

US3362124

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:36:21

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:27:22
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 23,25,27,29AUG2020 and 03,10SEP2020 is recorded under Illness Visit Day 3,5,7,9,14,21 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)	09 Dec 2020 06:21:40
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 23,25,27,29AUG2020 and 03,10SEP2020 is recorded under Illness Visit Day 3,5,7,9,14,21 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'Accession Number: 1F67708' (Site from DM).	Alexandra Caillouet (b) (4)	04 Dec 2020 17:43:38
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 23,25,27,29AUG2020 and 03,10SEP2020 is recorded under Illness Visit Day 3,5,7,9,14,21 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 06:05:17
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 23,25,27,29AUG2020 and 03SEP2020 is recorded under Illness Visit Day 3,5,7,9,14,21 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.' canceled (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 06:05:08

US3362124

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:36:21

[Visit](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 23,25,27,29AUG2020 and 03SEP2020 is recorded under Illness Visit Day 3,5,7,9,14,21 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 06:04:51
User accepted default value 'Day 3 (Day 3)'	Crystal Rowell (b) (4)	30 Sep 2020 15:22:55

US3362124

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:36:21

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:27:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
User closed query 'Per GCL Lab Recon: Saliva: The Collection dates for Illness visit day 3-21 = 21AUG2020 in PPD Central Lab, if EDC is correct kindly confirm if data can be updated in PPD via DCF. Thanks ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Mar 2021 08:47:47
Query 'Per GCL Lab Recon: Saliva: The Collection dates for Illness visit day 3-21 = 21AUG2020 in PPD Central Lab, if EDC is correct kindly confirm if data can be updated in PPD via DCF. Thanks ' answered with 'Confirmed as the correct dates. DCR will be submitted.' (Site from DM).	Alexandra Caillouet (b) (4)	22 Mar 2021 22:12:45
User opened query 'Per GCL Lab Recon: Saliva: The Collection dates for Illness visit day 3-21 = 21AUG2020 in PPD Central Lab, if EDC is correct kindly confirm if data can be updated in PPD via DCF. Thanks ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 05:55:39
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:09:12
User entered 'Yes (Y)'	Crystal Rowell (b) (4) (b) (4)	30 Sep 2020 15:22:55

US3362124

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:36:21

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:27:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 21AUG2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 09:23:53
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 21AUG2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'Illness visit occurred on 21 AUG 2020, therefore day 3 saliva was collected on 23 AUG 2020.' (Site from DM).	Alexandra Caillouet (b) (4)	10 Feb 2021 18:30:37
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 21AUG2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 04:08:42
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:09:12
User closed query 'Per GCL Lab Recon: GCL has a Saliva Day 21 sample with date of 21AUG2020 however it appears no dates are recorded on this log form. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 06:45:40
Query 'Per GCL Lab Recon: GCL has a Saliva Day 21 sample with date of 21AUG2020 however it appears no dates are recorded on this log form. Please reconcile.' answered with '21Aug not correct date, will submit DCR, saliva log updated' (Site from DM).	Crystal Rowell (b) (4) (b) (4)	03 Nov 2020 13:21:28
User entered '23 Aug 2020' reason for change: Per Query Resolution	(b) (4), (b) (6)	30 Oct 2020 19:50:53

US3362124

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:36:21

[Date of Collection](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Recon: GCL has a Saliva Day 21 sample with date of 21AUG2020 however it appears no dates are recorded on this log form. Please reconcile.' (Site from DM). User entered empty.	(b) (4), (b) (6) (b) (4)	25 Oct 2020 12:32:40
	Crystal Rowell (b) (4) (b) (4)	30 Sep 2020 15:22:55

US3362124

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:36:21

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:27:22
User accepted default value 'Day 5 (Day 5)'	Crystal Rowell (b) (4) (b) (4)	30 Sep 2020 15:22:55

US3362124

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:36:21

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:27:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	19 Nov 2020 18:09:12
User entered 'Yes (Y)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	03 Nov 2020 13:20:53
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 20:02:27
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	30 Sep 2020 15:22:55

US3362124

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:36:21

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:27:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	19 Nov 2020 18:09:12
User entered '25 Aug 2020' reason for change: Data Entry Error	Crystal Rowell (b) (4)	03 Nov 2020 13:20:53
User entered empty.	Crystal Rowell (b) (4)	30 Sep 2020 15:22:55

US3362124

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:36:21

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:27:22
User accepted default value 'Day 7 (Day 7)'	Crystal Rowell (b) (4) (b) (4)	30 Sep 2020 15:22:55

US3362124

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:36:21

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:27:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	19 Nov 2020 18:09:12
User entered 'Yes (Y)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	03 Nov 2020 13:20:53
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 20:02:27
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	30 Sep 2020 15:22:55

US3362124

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:36:21

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:27:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	19 Nov 2020 18:09:12
User entered '27 Aug 2020' reason for change: Data Entry Error	Crystal Rowell (b) (4)	03 Nov 2020 13:20:53
User entered empty.	Crystal Rowell (b) (4)	30 Sep 2020 15:22:55

US3362124

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:36:21

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:27:22
User accepted default value 'Day 9 (Day 9)'	Crystal Rowell (b) (4) (b) (4)	30 Sep 2020 15:22:55

US3362124

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:36:21

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:27:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	19 Nov 2020 18:09:12
User entered 'Yes (Y)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	03 Nov 2020 13:20:53
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 20:02:27
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	30 Sep 2020 15:22:55

US3362124

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:36:21

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:27:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:09:12
User entered '29 Aug 2020' reason for change: Data Entry Error	Crystal Rowell (b) (4)	03 Nov 2020 13:20:53
User entered empty.	(b) (4)	
	Crystal Rowell (b) (4)	30 Sep 2020 15:22:55
	(b) (4)	

US3362124

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:36:21

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:27:22
User accepted default value 'Day 14 (Day 14)'	Crystal Rowell (b) (4) (b) (4)	30 Sep 2020 15:22:55

US3362124

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:36:21

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:27:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:09:12
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	30 Sep 2020 15:22:55

US3362124

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:36:21

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:27:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:09:12
User entered '03 Sep 2020' reason for change: Per	(b) (4), (b) (6)	30 Oct 2020 19:54:30
Query Resolution		
User entered empty.	Crystal Rowell (b) (4)	30 Sep 2020 15:22:55
	(b) (4)	

US3362124

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:36:21

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:27:22
User accepted default value 'Day 21 (Day 21)'	Crystal Rowell (b) (4) (b) (4)	30 Sep 2020 15:22:55

US3362124

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:36:21

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:27:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:09:12
User entered 'Yes (Y)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	03 Nov 2020 13:20:53
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 20:02:27
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	30 Sep 2020 15:22:55
	(b) (4)	

US3362124

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:36:21

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:27:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:09:12
User entered '10 Sep 2020' reason for change: Data Entry Error	Crystal Rowell (b) (4)	03 Nov 2020 13:20:53
User entered empty.	(b) (4)	
	Crystal Rowell (b) (4)	30 Sep 2020 15:22:55
	(b) (4)	

US3362124

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:36:21

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:27:22
User accepted default value 'Day 28 (Day 28)'	Crystal Rowell (b) (4) (b) (4)	30 Sep 2020 15:22:55

US3362124

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:36:21

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:27:22
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 00:26:17
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Un-verified.	(b) (4) Alexandra Caillouet	15 Apr 2021 15:33:07
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Alexandra Caillouet	15 Apr 2021 15:33:07
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:05:46
DataPoint Un-verified.	Amy Thomassie (b) (4)	09 Apr 2021 14:11:10
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Amy Thomassie (b) (4)	09 Apr 2021 14:11:10
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:09:12
User entered 'No (N)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	19 Nov 2020 12:58:05
User entered 'Yes (Y)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	03 Nov 2020 13:20:53
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 20:02:27
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	30 Sep 2020 15:22:55

US3362124

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:36:21

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:27:22
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 00:26:17
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 18SEP2020 is recorded under Illness visit day 28 in EDC, however the same 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)	19 Apr 2021 05:57:21
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 18SEP2020 is recorded under Illness visit day 28 in EDC, however the same 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 'Corrected' (Site from DM).	Alexandra Caillouet (b) (4)	15 Apr 2021 15:37:03
DataPoint Un-verified.	Alexandra Caillouet (b) (4)	15 Apr 2021 15:33:07
User entered empty; reason for change Data Entry Error	Alexandra Caillouet (b) (4)	15 Apr 2021 15:33:07
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 18SEP2020 is recorded under Illness visit day 28 in EDC, however the same 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)	15 Apr 2021 04:58:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:05:46
User entered '18 Sep 2020' reason for change: Data Entry Error	Amy Thomassie (b) (4) (b) (4)	09 Apr 2021 14:11:10

US3362124

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:36:21

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Was Saliva Collected?' is noted as NO however Date of Collection is recorded. Please review and update accordingly. else clarify.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 17:23:40
Query 'Per CDM: Was Saliva Collected?' is noted as NO however Date of Collection is recorded. Please review and update accordingly. else clarify.' answered with 'updated' (Site from DM).	Amy Thomassie (b) (4)	23 Jan 2021 20:32:48
DataPoint Un-verified.	Amy Thomassie (b) (4)	23 Jan 2021 20:32:41
User entered empty; reason for change Data Entry Error	Amy Thomassie (b) (4)	23 Jan 2021 20:32:41
User opened query 'Per CDM: Was Saliva Collected?' is noted as NO however Date of Collection is recorded. Please review and update accordingly. else clarify.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 09:21:52
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:09:12
User entered '17 Sep 2020' reason for change: Data Entry Error	Crystal Rowell (b) (4)	03 Nov 2020 13:20:53
User entered empty.	Crystal Rowell (b) (4)	30 Sep 2020 15:22:55

US3362124

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:36:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:27:58
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
Query 'Per CDM: it appears that contact date and Illness VD1 date are the same (21AUG2020). Illness Visit should not be recorded until after positive result has been received; however it appears that Illness Visits were completed on day of diagnostic test where an Unscheduled Visit should have occurred. Please review and reconcile.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:34:41
User opened query 'Per CDM: it appears that contact date and Illness VD1 date are the same (21AUG2020). Illness Visit should not be recorded until after positive result has been received; however it appears that Illness Visits were completed on day of diagnostic test where an Unscheduled Visit should have occurred. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 12:07:51
Query 'Per CDM: it appears that contact date and Illness VD1 date are the same (21AUG2020)/ Illness Visit should not be recorded until after positive result has been received; however it appears that Illness Visits were completed on day of diagnostic test where an Unscheduled Visit should have occurred. Please review and reconcile.' canceled (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 12:07:45
User opened query 'Per CDM: it appears that contact date and Illness VD1 date are the same (21AUG2020)/ Illness Visit should not be recorded until after positive result has been received; however it appears that Illness Visits were completed on day of diagnostic test where an Unscheduled Visit should have occurred. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 12:06:45
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:30:51
User entered 'Yes (Y)'	Crystal Rowell (b) (4) (b) (4)	27 Aug 2020 16:49:09

US3362124

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:36:21

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:27:58
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:30:51
Query 'Per ETRTR: Please complete data entry in Saliva Collection page, thanks.' canceled (Site from CRA).	(b) (4), (b) (6)	09 Sep 2020 13:26:32
User opened query 'Per ETRTR: Please complete data entry in Saliva Collection page, thanks.' (Site from CRA).	(b) (4), (b) (6)	29 Aug 2020 16:12:51
User entered '21 Aug 2020'	Crystal Rowell (b) (4)	27 Aug 2020 16:49:09

US3362124

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:36:21

[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 04:27:58
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	09 Sep 2020 21:30:51
User entered 'Clinic (Clinic)'	Crystal Rowell (b) (4)	27 Aug 2020 16:49:09

US3362124

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:36:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:27:58
User entered 'SICKD1'	System	27 Aug 2020 16:49:09

US3362124

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:27:51
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:03:57
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	27 Aug 2020 16:52:05
	(b) (4)	

US3362124

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:27:51
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:03:57
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	12 Sep 2020 13:07:57
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	12 Sep 2020 13:07:57
User closed query 'The Assessment Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	12 Sep 2020 13:07:57
User entered '21 Aug 2020' reason for change: Data Entry Error	Amy Thomassie (b) (4) (b) (4)	12 Sep 2020 13:07:57
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	12 Sep 2020 13:07:39
User opened query 'The Assessment Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	12 Sep 2020 13:07:39
User closed query 'Data is required. Please provide.' (Site from System).	System	12 Sep 2020 13:07:39
User entered '21 Apr 2020' reason for change: Data Entry Error	Amy Thomassie (b) (4) (b) (4)	12 Sep 2020 13:07:39
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Aug 2020 16:52:05
User entered empty.	Crystal Rowell (b) (4) (b) (4)	27 Aug 2020 16:52:05

US3362124

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:27:51
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:03:57
User closed query 'Data is required. Please provide.' (Site from System).	System	12 Sep 2020 13:07:39
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	12 Sep 2020 13:07:39
User entered '09:20' reason for change: Data Entry Error	Amy Thomassie (b) (4) (b) (4)	12 Sep 2020 13:07:39
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Aug 2020 16:52:05
User entered empty.	Crystal Rowell (b) (4) (b) (4)	27 Aug 2020 16:52:05

US3362124

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:27:51
User entered '21 Aug 2020 09:20'	System	12 Sep 2020 13:07:57
User entered '21 Apr 2020 09:20'	System	12 Sep 2020 13:07:39
User entered empty.	System	27 Aug 2020 16:52:05

US3362124

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:27:51
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:03:57
User closed query 'Data is required. Please provide.' (Site from System).	System	12 Sep 2020 13:07:39
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	12 Sep 2020 13:07:39
User entered '181.0' cm reason for change: Data Entry Error	Amy Thomassie (b) (4) (b) (4)	12 Sep 2020 13:07:39
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Aug 2020 16:52:05
User entered empty.	Crystal Rowell (b) (4) (b) (4)	27 Aug 2020 16:52:05
DataPoint set to visible.	System	27 Aug 2020 16:49:09

US3362124

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:27:51
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:03:57
User closed query 'Data is required. Please provide.' (Site from System).	System	12 Sep 2020 13:07:39
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	12 Sep 2020 13:07:39
User entered '90.2' kg reason for change: Data Entry Error	Amy Thomassie (b) (4) (b) (4)	12 Sep 2020 13:07:39
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Aug 2020 16:52:05
User entered empty.	Crystal Rowell (b) (4) (b) (4)	27 Aug 2020 16:52:05
DataPoint set to visible.	System	27 Aug 2020 16:49:09

US3362124

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:27:51
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:03:57
User entered '37.5' C reason for change: Data Entry Error	Amy Thomassie (b) (4)	12 Sep 2020 13:07:39
	(b) (4)	
User entered '99' F	Crystal Rowell (b) (4)	27 Aug 2020 16:52:05
	(b) (4)	

US3362124

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:27:51
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 21:03:57
User closed query 'Data is required. Please provide.' (Site from System).	System	12 Sep 2020 13:07:39
Query 'Data is required. Please provide.' answered by System data change (Site from System).		12 Sep 2020 13:07:39
User entered 'Oral (Oral)' reason for change: Data Entry Error	Amy Thomassie (b) (4)	12 Sep 2020 13:07:39
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Aug 2020 16:52:05
User entered empty.	Crystal Rowell (b) (4)	27 Aug 2020 16:52:05

US3362124

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:27:51
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	04 Nov 2020 21:03:57
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 16:52:05
	Crystal Rowell (b) (4)	
	(b) (4)	

US3362124

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:27:51
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:03:57
User closed query 'Data is required. Please provide.' (Site from System).	System	12 Sep 2020 13:07:39
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	12 Sep 2020 13:07:39
User entered '86' reason for change: Data Entry Error	Amy Thomassie (b) (4) (b) (4)	12 Sep 2020 13:07:39
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Aug 2020 16:52:05
User entered empty.	Crystal Rowell (b) (4) (b) (4)	27 Aug 2020 16:52:05

US3362124

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:27:51
User entered 'bpm'	System	12 Sep 2020 13:07:39
User entered empty.	System	27 Aug 2020 16:52:05

US3362124

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:27:51
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:03:57
User closed query 'Data is required. Please provide.' (Site from System).	System	12 Sep 2020 13:07:39
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	12 Sep 2020 13:07:39
User entered '18' reason for change: Data Entry Error	Amy Thomassie (b) (4) (b) (4)	12 Sep 2020 13:07:39
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Aug 2020 16:52:05
User entered empty.	Crystal Rowell (b) (4) (b) (4)	27 Aug 2020 16:52:05

US3362124

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:27:51
User entered 'breaths/min'	System	12 Sep 2020 13:07:39
User entered empty.	System	27 Aug 2020 16:52:05

US3362124

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:27:51
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:03:57
User closed query 'Data is required. Please provide.' (Site from System).	System	12 Sep 2020 13:07:39
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	12 Sep 2020 13:07:39
User entered '132' reason for change: Data Entry Error	Amy Thomassie (b) (4) (b) (4)	12 Sep 2020 13:07:39
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Aug 2020 16:52:05
User entered empty.	Crystal Rowell (b) (4) (b) (4)	27 Aug 2020 16:52:05

US3362124

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:27:51
User entered 'mmHg'	System	12 Sep 2020 13:07:39
User entered empty.	System	27 Aug 2020 16:52:05

US3362124

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:27:51
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:03:57
User closed query 'Data is required. Please provide.' (Site from System).	System	12 Sep 2020 13:07:39
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	12 Sep 2020 13:07:39
User entered '84' reason for change: Data Entry Error	Amy Thomassie (b) (4) (b) (4)	12 Sep 2020 13:07:39
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Aug 2020 16:52:05
User entered empty.	Crystal Rowell (b) (4) (b) (4)	27 Aug 2020 16:52:05

US3362124

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:27:51
User entered 'mmHg'	System	12 Sep 2020 13:07:39
User entered empty.	System	27 Aug 2020 16:52:05

US3362124

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:27:51

US3362124

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:27:51

US3362124

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:36:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:27:39
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Sep 2020 21:31:12
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	27 Aug 2020 16:52:19
	(b) (4)	

US3362124

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:36:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:27:39
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:31:12
User entered '21 Aug 2020'	Crystal Rowell (b) (4)	27 Aug 2020 16:52:19

US3362124

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:36:21

[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 04:27:32
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	09 Sep 2020 21:31:18
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	27 Aug 2020 16:52:31
	(b) (4)	

US3362124

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:36:21

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:27:32
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	09 Sep 2020 21:31:18
User entered '21 Aug 2020'	Crystal Rowell (b) (4)	27 Aug 2020 16:52:31
	(b) (4)	

US3362124

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:36:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:56
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:06:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 20:02:04

US3362124

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:56
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:06:32
User entered '18 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 20:02:04

US3362124

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:36:21

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:56
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:06:32
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	24 Sep 2020 20:02:04

US3362124

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:36:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:56
User entered 'SICKD28'	System	24 Sep 2020 20:02:04

US3362124

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:56
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:07:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 20:08:08

US3362124

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:56
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:07:04
User entered '18 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 20:08:08

US3362124

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:56
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:07:04
User entered '14:54'	(b) (4), (b) (6)	24 Sep 2020 20:08:08

US3362124

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:56
User entered '18 Sep 2020 14:54'	System	24 Sep 2020 20:08:08

US3362124

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:56
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:07:04
User entered '181' cm	(b) (4), (b) (6)	24 Sep 2020 20:08:08
DataPoint set to visible.	System	24 Sep 2020 20:02:04

US3362124

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:56
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:07:04
User entered '90.2' kg	(b) (4), (b) (6)	24 Sep 2020 20:08:08
DataPoint set to visible.	System	24 Sep 2020 20:02:04

US3362124

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:56
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:07:04
User entered '37.1' C	(b) (4), (b) (6)	24 Sep 2020 20:08:08

US3362124

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:56
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:07:04
User entered 'Oral (Oral)'	(b) (4), (b) (6)	24 Sep 2020 20:08:08

US3362124

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:56
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:07:04
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:08:08

US3362124

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:56
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:07:04
User entered '98'	(b) (4), (b) (6)	24 Sep 2020 20:08:08

US3362124

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:56
User entered 'bpm'	System	24 Sep 2020 20:08:08

US3362124

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:56
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:07:04
User entered '17'	(b) (4), (b) (6)	24 Sep 2020 20:08:08

US3362124

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:56
User entered 'breaths/min'	System	24 Sep 2020 20:08:08

US3362124

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:56
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:07:04
User entered '122'	(b) (4), (b) (6)	24 Sep 2020 20:08:08

US3362124

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:56
User entered 'mmHg'	System	24 Sep 2020 20:08:08

US3362124

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:56
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:07:04
User entered '79'	(b) (4), (b) (6)	24 Sep 2020 20:08:08

US3362124

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:56
User entered 'mmHg'	System	24 Sep 2020 20:08:08

US3362124

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:56

US3362124

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:56

US3362124

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:36:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:56
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:07:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 20:08:17

US3362124

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:36:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:56
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:07:46
User entered '18 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 20:08:17

US3362124

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:36:21

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:56
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:07:52
User entered 'Yes (Y)'	Crystal Rowell (b) (4) (b) (4)	30 Sep 2020 15:22:43

US3362124

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:36:21

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:56
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 18 SEP 2020 is reported under Convalescence Visit Day 28 in EDC, however the same is reported in the Illness Visit Day 1 in PPD Central lab. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 08:15:55
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 18 SEP 2020 is reported under Convalescence Visit Day 28 in EDC, however the same is reported in the Illness Visit Day 1 in PPD Central lab. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'DCF submitted' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 16:56:03
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 18 SEP 2020 is reported under Convalescence Visit Day 28 in EDC, however the same is reported in the Illness Visit Day 1 in PPD Central lab. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 05:40:21
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:07:52
User entered '18 Sep 2020'	Crystal Rowell (b) (4) (b) (4)	30 Sep 2020 15:22:43

US3362124

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

Form: Visit Date

Generated On: 11 Aug 2021 22:36:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:06:02
User entered 'Yes (Y)'	Alexandra Caillouet	25 Jan 2021 21:09:56
	(b) (4)	

US3362124

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

Form: Visit Date

Generated On: 11 Aug 2021 22:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:06:02
User entered '25 Jan 2021'	Alexandra Caillouet (b) (4)	25 Jan 2021 21:09:56

US3362124

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

Form: Visit Date

Generated On: 11 Aug 2021 22:36:21

[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 11:25:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:06:02
User entered 'Clinic (Clinic)'	Alexandra Caillouet (b) (4)	25 Jan 2021 21:09:56

US3362124

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

Form: Visit Date

Generated On: 11 Aug 2021 22:36:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User entered 'UNBLND_DECIDE'	System	25 Jan 2021 21:09:56

US3362124

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

Form: Unblinding

Generated On: 11 Aug 2021 22:36:21

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:06:08
User entered '25 Jan 2021'	Alexandra Caillouet (b) (4)	25 Jan 2021 21:10:51

US3362124

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

Form: Unblinding

Generated On: 11 Aug 2021 22:36:21

[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 11:25:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:27:53

US3362124

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

Form: Unblinding

Generated On: 11 Aug 2021 22:36:21

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:06:08
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	25 Jan 2021 21:10:51

US3362124

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

Form: Unblinding

Generated On: 11 Aug 2021 22:36:21

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:27:53

US3362124

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

Form: Unblinding

Generated On: 11 Aug 2021 22:36:21

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:06:08
User entered '25 Jan 2021'	Alexandra Caillouet (b) (4)	25 Jan 2021 21:10:51

US3362124

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

Form: Unblinding

Generated On: 11 Aug 2021 22:36:21

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:06:08
User entered 'mRNA-1273 (mRNA-1273)' reason for change: Data Entry Error	Alexandra Caillouet	29 Mar 2021 20:38:56
User entered 'Placebo (Placebo)'	(b) (4)	
	Alexandra Caillouet	25 Jan 2021 21:10:51
	(b) (4)	

US3362124

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

Form: Unblinding

Generated On: 11 Aug 2021 22:36:21

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:06:08
User entered 'mRNA-1273 (mRNA-1273)' reason for change: Data Entry Error	Alexandra Caillouet	29 Mar 2021 20:38:56
User entered 'Placebo (Placebo)'	(b) (4)	
	Alexandra Caillouet	25 Jan 2021 21:10:51
	(b) (4)	

US3362124

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

Form: Unblinding

Generated On: 11 Aug 2021 22:36:21

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:06:08
User entered 'Not Administered (NA)' reason for change: Data Entry Error	Alexandra Caillouet	29 Mar 2021 20:34:52
User entered 'Placebo (Placebo)'	(b) (4)	
	Alexandra Caillouet	25 Jan 2021 21:10:51
	(b) (4)	

US3362124

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

Form: Unblinding

Generated On: 11 Aug 2021 22:36:21

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:06:08
User entered 'Yes (Y)'	Alexandra Caillouet	25 Jan 2021 21:10:51
	(b) (4)	

US3362124

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

Form: Unblinding

Generated On: 11 Aug 2021 22:36:21

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User entered empty.	System	29 Mar 2021 20:38:56
User entered 'I'	System	25 Jan 2021 21:10:51

US3362124

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

Form: Unblinding

Generated On: 11 Aug 2021 22:36:21

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User entered 'I'	System	25 Jan 2021 21:10:51

US3362124

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:36:21

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:07:01
User entered missing code ND - Not Done.	Alexandra Caillouet (b) (4)	25 Jan 2021 21:13:05

US3362124

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:36:21

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:07:01
User entered missing code ND - Not Done.	Alexandra Caillouet (b) (4)	25 Jan 2021 21:13:05

US3362124

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:36:21

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User entered empty.	System	25 Jan 2021 21:13:05
DataPoint set to visible.	System	25 Jan 2021 21:10:51

US3362124

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:36:21

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:07:01
User entered missing code ND - Not Done.	Alexandra Caillouet (b) (4)	25 Jan 2021 21:13:05

US3362124

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:36:21

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:07:01
User entered missing code ND - Not Done.	Alexandra Caillouet	25 Jan 2021 21:13:05
	(b) (4)	

US3362124

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:36:21

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User entered empty.	System	25 Jan 2021 21:13:05
DataPoint set to visible.	System	25 Jan 2021 21:10:51

US3362124

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User accepted default value 'Pre-Dose (PREDOSE)'	Alexandra Caillouet (b) (4)	25 Jan 2021 21:13:05

US3362124

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:07:01
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	25 Jan 2021 21:13:05

US3362124

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:21

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:07:01
User entered '25 Jan 2021'	Alexandra Caillouet (b) (4)	25 Jan 2021 21:13:05

US3362124

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:21

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:07:01
User entered '09:05'	Alexandra Caillouet (b) (4)	25 Jan 2021 21:13:05

US3362124

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User entered '25 Jan 2021 09:05'	System	25 Jan 2021 21:13:05

US3362124

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:21

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:07:01
User entered '36.4' C	Alexandra Caillouet (b) (4)	25 Jan 2021 21:13:05

US3362124

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:07:01
User entered 'Oral (Oral)'	Alexandra Caillouet (b) (4)	25 Jan 2021 21:13:05

US3362124

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:07:01
User entered empty.	Alexandra Caillouet (b) (4)	25 Jan 2021 21:13:05

US3362124

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:07:01
User entered '61'	Alexandra Caillouet (b) (4)	25 Jan 2021 21:13:05

US3362124

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User entered 'bpm'	System	25 Jan 2021 21:13:05

US3362124

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:07:01
User entered '17'	Alexandra Caillouet (b) (4)	25 Jan 2021 21:13:05

US3362124

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User entered 'breaths/min'	System	25 Jan 2021 21:13:05

US3362124

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:21

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:07:01
User entered '124'	Alexandra Caillouet	25 Jan 2021 21:13:05
	(b) (4)	

US3362124

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User entered 'mmHg'	System	25 Jan 2021 21:13:05

US3362124

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:21

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:07:01
User entered '92'	Alexandra Caillouet (b) (4)	25 Jan 2021 21:13:05

US3362124

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User entered 'mmHg'	System	25 Jan 2021 21:13:05

US3362124

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:36:21

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:07:01
User entered missing code ND - Not Done.	Alexandra Caillouet (b) (4)	25 Jan 2021 21:13:05

US3362124

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:36:21

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:07:01
User entered missing code ND - Not Done.	Alexandra Caillouet (b) (4)	25 Jan 2021 21:13:05

US3362124

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:36:21

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User entered empty.	System	25 Jan 2021 21:13:05
DataPoint set to visible.	System	25 Jan 2021 21:10:51

US3362124

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User accepted default value 'Post-Dose (POSTDOSE)'	Alexandra Caillouet (b) (4)	25 Jan 2021 21:13:05

US3362124

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:07:01
User entered 'Yes (Y)'	Alexandra Caillouet	25 Jan 2021 21:13:05
	(b) (4)	

US3362124

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:21

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:07:01
User entered '25 Jan 2021'	Alexandra Caillouet (b) (4)	25 Jan 2021 21:13:05

US3362124

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:21

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:07:01
User entered '10:21'	Alexandra Caillouet (b) (4)	25 Jan 2021 21:13:05

US3362124

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User entered '25 Jan 2021 10:21'	System	25 Jan 2021 21:13:05

US3362124

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:21

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:07:01
User entered '36.9' C	Alexandra Caillouet (b) (4)	25 Jan 2021 21:13:05

US3362124

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:07:01
User entered 'Oral (Oral)'	Alexandra Caillouet (b) (4)	25 Jan 2021 21:13:05

US3362124

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:07:01
User entered empty.	Alexandra Caillouet (b) (4)	25 Jan 2021 21:13:05

US3362124

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:07:01
User entered '60'	Alexandra Caillouet (b) (4)	25 Jan 2021 21:13:05

US3362124

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User entered 'bpm'	System	25 Jan 2021 21:13:05

US3362124

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:07:01
User entered '18'	Alexandra Caillouet (b) (4)	25 Jan 2021 21:13:05

US3362124

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User entered 'breaths/min'	System	25 Jan 2021 21:13:05

US3362124

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:21

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:07:01
User entered '120'	Alexandra Caillouet	25 Jan 2021 21:13:05
	(b) (4)	

US3362124

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User entered 'mmHg'	System	25 Jan 2021 21:13:05

US3362124

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:21

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:07:01
User entered '83'	Alexandra Caillouet (b) (4)	25 Jan 2021 21:13:05

US3362124

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User entered 'mmHg'	System	25 Jan 2021 21:13:05

US3362124

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:36:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:07:09
User entered 'No (N)'	Alexandra Caillouet (b) (4)	25 Jan 2021 21:14:00

US3362124

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:36:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:07:09
User entered empty.	Alexandra Caillouet (b) (4)	25 Jan 2021 21:14:00

US3362124

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

Form: Exposure

Generated On: 11 Aug 2021 22:36:21

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:07:25
User entered 'Yes (Y)'	Alexandra Caillouet	25 Jan 2021 21:15:01
	(b) (4)	

US3362124

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

Form: Exposure

Generated On: 11 Aug 2021 22:36:21

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:07:25
User entered empty.	Alexandra Caillouet (b) (4)	25 Jan 2021 21:15:01

US3362124

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

Form: Exposure

Generated On: 11 Aug 2021 22:36:21

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 11:25:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:07:25
User entered empty.	Alexandra Caillouet	25 Jan 2021 21:15:01
	(b) (4)	

US3362124

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

Form: Exposure

Generated On: 11 Aug 2021 22:36:21

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User entered 'mRNA-1273'	System	25 Jan 2021 21:15:01
DataPoint set to visible.	System	25 Jan 2021 21:10:51

US3362124

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

Form: Exposure

Generated On: 11 Aug 2021 22:36:21

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:07:25
User entered '25 Jan 2021'	Alexandra Caillouet (b) (4)	25 Jan 2021 21:15:01

US3362124

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

Form: Exposure

Generated On: 11 Aug 2021 22:36:21

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:07:25
User entered '09:44'	Alexandra Caillouet (b) (4)	25 Jan 2021 21:15:01

US3362124

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

Form: Exposure

Generated On: 11 Aug 2021 22:36:21

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User entered '25 Jan 2021 09:44'	System	25 Jan 2021 21:15:01

US3362124

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

Form: Exposure

Generated On: 11 Aug 2021 22:36:21

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:07:25
User entered 'Left Arm (LEFT ARM)'	Alexandra Caillouet	25 Jan 2021 21:15:01
	(b) (4)	

US3362124

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

Form: Exposure

Generated On: 11 Aug 2021 22:36:21

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:07:25
User entered 'ONCE'	System	25 Jan 2021 21:15:01

US3362124

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

Form: Exposure

Generated On: 11 Aug 2021 22:36:21

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User entered 'INTRAMUSCULAR'	System	25 Jan 2021 21:15:01

US3362124

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:36:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:08:16
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	25 Jan 2021 21:10:25

US3362124

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:36:21

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:08:16
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 25Jan2021 is recorded under OL-1 visit in EDC, however the same is reported under OL-1 Visit with date 08Jan2021 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 13:10:41
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 25Jan2021 is recorded under OL-1 visit in EDC, however the same is reported under OL-1 Visit with date 08Jan2021 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' answered with 'Accession Number: 1F67708' (Site from DM).	Alexandra Caillouet (b) (4)	05 Feb 2021 23:03:44
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 25Jan2021 is recorded under OL-1 visit in EDC, however the same is reported under OL-1 Visit with date 08Jan2021 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 12:41:49
User entered '25 Jan 2021'	Alexandra Caillouet (b) (4)	25 Jan 2021 21:10:25

US3362124

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:36:21

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:08:16
User entered '08:57'	Alexandra Caillouet (b) (4)	25 Jan 2021 21:10:25

US3362124

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:36:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User entered '25 Jan 2021 08:57'	System	25 Jan 2021 21:10:25

US3362124

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:36:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:08:23
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	25 Jan 2021 21:10:37

US3362124

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:08:23
User entered '25 Jan 2021'	Alexandra Caillouet (b) (4)	25 Jan 2021 21:10:37

US3362124

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:36:21

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:08:23
User entered '08:53'	Alexandra Caillouet (b) (4)	25 Jan 2021 21:10:37

US3362124

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:36:21

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User entered '25 Jan 2021 08:53'	System	25 Jan 2021 21:10:37

US3362124

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

Form: Continuing

Generated On: 11 Aug 2021 22:36:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:08:30
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	25 Jan 2021 21:15:06

US3362124

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

Form: Continuing

Generated On: 11 Aug 2021 22:36:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:43
User entered 'I'	System	25 Jan 2021 21:15:06

US3362124

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:44
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:20
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:09:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Feb 2021 22:06:32

US3362124

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:21

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:44
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:20
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:09:56
User entered '1 Feb 2021'	(b) (4), (b) (6)	01 Feb 2021 22:06:32

US3362124

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:44
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:20
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:09:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	01 Feb 2021 22:06:32

US3362124

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:44
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:20
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:09:56
User entered empty.	(b) (4), (b) (6)	01 Feb 2021 22:06:32

US3362124

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:44
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:20
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:10:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Feb 2021 22:06:38

US3362124

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:44
User entered 'I'	System	01 Feb 2021 22:06:38

US3362124

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:21

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:44
User entered '1'	System	01 Feb 2021 22:06:38
DataPoint set to visible.	System	01 Feb 2021 22:06:38

US3362124

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:36:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:10:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Feb 2021 16:32:52

US3362124

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:10:28
User entered '23 Feb 2021'	(b) (4), (b) (6)	23 Feb 2021 16:32:52

US3362124

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:36:21

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:10:28
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	23 Feb 2021 16:32:52

US3362124

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:36:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User entered 'OLD29'	System	23 Feb 2021 16:32:52

US3362124

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:10:48
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	29 Mar 2021 20:40:47

US3362124

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:10:48
User entered '23 Feb 2021'	Alexandra Caillouet (b) (4)	29 Mar 2021 20:40:47

US3362124

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:10:48
User entered '09:15'	Alexandra Caillouet (b) (4)	29 Mar 2021 20:40:47

US3362124

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User entered '23 Feb 2021 09:15'	System	29 Mar 2021 20:40:47

US3362124

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:10:48
User entered '37.0' C	Alexandra Caillouet (b) (4)	29 Mar 2021 20:40:47

US3362124

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:10:48
User entered 'Oral (Oral)'	Alexandra Caillouet (b) (4)	29 Mar 2021 20:40:47

US3362124

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:10:48
User entered empty.	Alexandra Caillouet (b) (4)	29 Mar 2021 20:40:47

US3362124

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:10:48
User entered '76'	Alexandra Caillouet (b) (4)	29 Mar 2021 20:40:47

US3362124

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User entered 'bpm'	System	29 Mar 2021 20:40:47

US3362124

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:10:48
User entered '16'	Alexandra Caillouet (b) (4)	29 Mar 2021 20:40:47

US3362124

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User entered 'breaths/min'	System	29 Mar 2021 20:40:47

US3362124

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:10:48
User entered '124'	Alexandra Caillouet (b) (4)	29 Mar 2021 20:40:47

US3362124

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User entered 'mmHg'	System	29 Mar 2021 20:40:47

US3362124

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:10:48
User entered '69'	Alexandra Caillouet (b) (4)	29 Mar 2021 20:40:47

US3362124

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User entered 'mmHg'	System	29 Mar 2021 20:40:47

US3362124

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10

US3362124

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:21

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10

US3362124

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	23 Feb 2021 16:40:27

US3362124

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:11:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Feb 2021 16:40:27

US3362124

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:21

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:11:25
User entered '23 Feb 2021'	(b) (4), (b) (6)	23 Feb 2021 16:40:27

US3362124

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:11:25
User entered '09:15'	(b) (4), (b) (6)	23 Feb 2021 16:40:27

US3362124

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User entered '23 Feb 2021 09:15'	System	23 Feb 2021 16:40:27

US3362124

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:21

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:11:25
User entered '37.0' C	(b) (4), (b) (6)	23 Feb 2021 16:40:27

US3362124

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:11:25
User entered 'Oral (Oral)'	(b) (4), (b) (6)	23 Feb 2021 16:40:27

US3362124

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:11:25
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 16:40:27

US3362124

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:11:25
User entered '76'	(b) (4), (b) (6)	23 Feb 2021 16:40:27

US3362124

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User entered 'bpm'	System	23 Feb 2021 16:40:27

US3362124

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:11:25
User entered '16'	(b) (4), (b) (6)	23 Feb 2021 16:40:27

US3362124

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User entered 'breaths/min'	System	23 Feb 2021 16:40:27

US3362124

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:21

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:11:25
User entered '124'	(b) (4), (b) (6)	23 Feb 2021 16:40:27

US3362124

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User entered 'mmHg'	System	23 Feb 2021 16:40:27

US3362124

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:21

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:11:25
User entered '69'	(b) (4), (b) (6)	23 Feb 2021 16:40:27

US3362124

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User entered 'mmHg'	System	23 Feb 2021 16:40:27

US3362124

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	23 Feb 2021 16:40:27

US3362124

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:11:25
User closed query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	System	23 Feb 2021 16:40:40
User opened query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	System	23 Feb 2021 16:40:27
User entered 'No (N)'	(b) (4), (b) (6)	23 Feb 2021 16:40:27

US3362124

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:11:25
User entered empty; reason for change Data Entry Error		23 Feb 2021 16:40:40
User entered '23 Feb 2021'		23 Feb 2021 16:40:27

US3362124

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:21

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:11:25
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 16:40:27

US3362124

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User entered empty.	System	23 Feb 2021 16:40:27

US3362124

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:21

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:11:25
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 16:40:27

US3362124

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:11:25
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 16:40:27

US3362124

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:11:25
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 16:40:27

US3362124

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:11:25
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 16:40:27

US3362124

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User entered empty.	System	23 Feb 2021 16:40:27

US3362124

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:11:25
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 16:40:27

US3362124

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User entered empty.	System	23 Feb 2021 16:40:27

US3362124

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:21

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:11:25
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 16:40:27

US3362124

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User entered empty.	System	23 Feb 2021 16:40:27

US3362124

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:21

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:11:25
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 16:40:27

US3362124

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User entered empty.	System	23 Feb 2021 16:40:27

US3362124

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:36:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:11:30
User entered 'No (N)'	(b) (4), (b) (6)	23 Feb 2021 17:08:47

US3362124

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:36:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:11:30
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 17:08:47

US3362124

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:36:21

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:11:36
User entered 'No (N)'	(b) (4), (b) (6)	23 Feb 2021 16:40:52

US3362124

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:36:21

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:11:36
User closed query 'Was study treatment given? is No, System however If No, reason not given is not provided. Please review and reconcile.' (Site from System).		23 Feb 2021 17:29:42
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 17:29:42
User opened query 'Was study treatment given? is No, however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	System	23 Feb 2021 16:40:52
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 16:40:52

US3362124

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:11:36
User entered 'Patient received 1st dose on 13AUG2020 during Blinded Phase, and 2nd dose on 25JAN2021 during Open-Label Phase.' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 17:29:42
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 16:40:52

US3362124

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:36:21

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
DataPoint set to visible.	System	29 Mar 2021 20:38:56
User entered empty.	System	23 Feb 2021 16:40:52
DataPoint set to invisible.	System	01 Feb 2021 22:06:38

US3362124

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:36:21

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:11:36
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 16:40:52

US3362124

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:36:21

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:11:36
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 16:40:52

US3362124

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:36:21

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User entered empty.	System	23 Feb 2021 16:40:52

US3362124

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:36:21

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:11:36
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 16:40:52

US3362124

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:36:21

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:11:36
User entered empty.	System	23 Feb 2021 16:40:52

US3362124

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:36:21

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User entered empty.	System	23 Feb 2021 16:40:52

US3362124

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:36:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:11:44
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	29 Mar 2021 20:42:01

US3362124

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:36:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:11:44
User entered '23 Feb 2021'	Alexandra Caillouet (b) (4)	29 Mar 2021 20:42:01

US3362124

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:36:21

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:11:44
User entered '09:23'	Alexandra Caillouet (b) (4)	29 Mar 2021 20:42:01

US3362124

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:36:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User entered '23 Feb 2021 09:23'	System	29 Mar 2021 20:42:01

US3362124

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	12 Apr 2021 19:11:51
User entered 'No (N)' reason for change: Data Entry Error	Alexandra Caillouet	29 Mar 2021 20:36:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Feb 2021 17:30:04

US3362124

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:10
User entered empty.	System	29 Mar 2021 20:36:52
User entered '1'	System	23 Feb 2021 17:30:04

US3362124

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:12:09
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	30 Mar 2021 16:47:44
User entered 'No (N)' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	29 Mar 2021 20:45:17
Query 'Data is required. Please complete.' answered with 'Subject did not require OL-D36 call as they were not injected with vaccine during OL-D29. PATIENT RECEIVED 1ST DOSE ON 13AUG2020 DURING BLINDED PHASE, AND 2ND DOSE ON 25JAN2021 DURING OPEN-LABEL PHASE.' (Site from System).	Alexandra Caillouet (b) (4)	29 Mar 2021 20:43:40
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Mar 2021 20:37:19
User entered empty; reason for change Data Entry Error	Alexandra Caillouet (b) (4)	29 Mar 2021 20:37:19
User entered 'No (N)'	Alexandra Caillouet (b) (4)	29 Mar 2021 20:32:43

US3362124

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:21

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:12:09
User entered empty.	Alexandra Caillouet	29 Mar 2021 20:32:43
	(b) (4)	

US3362124

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:12:09
User entered empty.	Alexandra Caillouet	29 Mar 2021 20:32:43
	(b) (4)	

US3362124

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:12:09
User entered empty.	Alexandra Caillouet	29 Mar 2021 20:32:43
	(b) (4)	

US3362124

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:12:15
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Mar 2021 20:45:22
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Mar 2021 20:45:22
User entered 'No (N)' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	29 Mar 2021 20:45:22
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Mar 2021 20:37:25
User entered empty; reason for change Data Entry Error	Alexandra Caillouet (b) (4)	29 Mar 2021 20:37:25
User entered 'No (N)' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	29 Mar 2021 20:36:58
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	29 Mar 2021 20:32:54

US3362124

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:21

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 20:36:58
User entered 'l'	System	29 Mar 2021 20:32:54

US3362124

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:36:21

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:26:42
User closed query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's Dose 1 diary Joint aches in several joints lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked.	(b) (4), (b) (6)	20 Apr 2021 16:47:45
' (Site from DM). Query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's Dose 1 diary Joint aches in several joints lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked.	Alexandra Caillouet (b) (4)	19 Apr 2021 20:10:27
' answered with 'Will update AE log. ' (Site from DM). User opened query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's Dose 1 diary Joint aches in several joints lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked.	(b) (4), (b) (6)	19 Apr 2021 03:00:01
' (Site from DM). User signature succeeded.	Jordan Whatley (b) (4) (b) (4)	13 Mar 2021 22:13:51
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:53
User entered 'Yes (Y)'	Crystal Rowell (b) (4) (b) (4)	27 Aug 2020 16:17:02

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2157 of 2410

US3362124

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:21

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:25:40
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:15:56
User entered	System	27 Aug 2020 17:14:35
'USA-US112-2020-mRNA-1273-P301000001'		
User entered 'New'	(b) (4), (b) (6)	27 Aug 2020 17:14:35

US3362124

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:21

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:12:49
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:51
User closed query 'Per CDM: Please consider updating to either Symptomatic Covid-19 or Coviud-19' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:06:31
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 21:38:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 21:38:18
Data point term sent to Coder	System	23 Nov 2020 16:43:52
Query 'Per CDM: Please consider updating to either Symptomatic Covid-19 or Coviud-19' answered with 'updated' (Site from DM).	Alexandra Caillouet (b) (4)	23 Nov 2020 16:43:51
DataPoint Un-verified.	Alexandra Caillouet (b) (4)	23 Nov 2020 16:43:46
Coding entries removed.	Alexandra Caillouet (b) (4)	23 Nov 2020 16:43:46
User entered 'Symptomatic COVID 19' reason for change: Per Query Resolution	Alexandra Caillouet (b) (4)	23 Nov 2020 16:43:46
User opened query 'Per CDM: Please consider updating to either Symptomatic Covid-19 or Coviud-19' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 09:47:49
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:10:54
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Nov 2020 18:35:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Nov 2020 18:35:35
Data point term sent to Coder	System	09 Nov 2020 18:20:03
User closed query 'For consistency, please update to Covid 19 Infection.' (Site from System).	System	09 Nov 2020 18:19:46
Query 'For consistency, please update to Covid 19 Infection.' answered with 'Updated per query' (Site from System).	Alexandra Caillouet (b) (4)	09 Nov 2020 18:19:46
DataPoint Un-verified.	Alexandra Caillouet (b) (4)	09 Nov 2020 18:19:27

US3362124

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:21

[Adverse event](#)

Audit	User	Time (GMT)
Coding entries removed.	Alexandra Caillouet	09 Nov 2020 18:19:27
	(b) (4)	
User entered 'Covid 19 Infection' reason for change: Per Query Resolution	Alexandra Caillouet	09 Nov 2020 18:19:27
	(b) (4)	
User opened query 'For consistency, please update to Covid 19 Infection.' (Site from System).	Coder Import (b) (4)	07 Nov 2020 19:35:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:25:40
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: SARS-CoV-2 infection - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 12:41:36
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 12:41:36
	(b) (4)	
Data point term sent to Coder	System	27 Aug 2020 16:18:54
User entered 'SARS COV 2 infection'	Crystal Rowell (b) (4)	27 Aug 2020 16:18:18
	(b) (4)	

US3362124

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:25:40
User entered 'Yes (Y)'	Crystal Rowell (b) (4) (b) (4)	27 Aug 2020 16:18:18

US3362124

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:25:40
User entered 'No (N)'	Crystal Rowell (b) (4) (b) (4)	27 Aug 2020 16:18:18

US3362124

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:25:40
User entered 'Yes (Y)'	Crystal Rowell (b) (4) (b) (4)	27 Aug 2020 16:18:18

US3362124

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:25:40
User entered '18 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Nov 2020 21:23:43
User entered '21 Aug 2020'	Crystal Rowell (b) (4)	27 Aug 2020 16:18:18
	(b) (4)	

US3362124

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:21

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:25:40
User entered empty.	Crystal Rowell (b) (4) (b) (4)	27 Aug 2020 16:18:18

US3362124

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:21

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 16:18:18

US3362124

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:25:40
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	27 Aug 2020 16:24:44
User entered 'No (N)' reason for change: Data Entry Error	Crystal Rowell (b) (4) (b) (4)	27 Aug 2020 16:24:44
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	27 Aug 2020 16:24:34
User entered 'Yes (Y)'	Crystal Rowell (b) (4) (b) (4)	27 Aug 2020 16:18:18

US3362124

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:25:40
User entered '18 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Nov 2020 21:23:43
User closed query 'Per ETRTR: Please confirm whether a test was done to confirm negative COVID (Saliva or PCR Swab), thanks.' (Site from CRA).	(b) (4), (b) (6)	06 Sep 2020 18:40:09
Query 'Per ETRTR: Please confirm whether a test was done to confirm negative COVID (Saliva or PCR Swab), thanks.' answered with 'confirm positive, PCR swab' (Site from CRA).	(b) (4), (b) (6)	03 Sep 2020 18:04:26
User opened query 'Per ETRTR: Please confirm whether a test was done to confirm negative COVID (Saliva or PCR Swab), thanks.' (Site from CRA).	(b) (4), (b) (6)	29 Aug 2020 16:28:17
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	27 Aug 2020 16:24:34
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	27 Aug 2020 16:24:34
User entered '24 Aug 2020' reason for change: Data Entry Error	Crystal Rowell (b) (4)	27 Aug 2020 16:24:34
	(b) (4)	
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	27 Aug 2020 16:24:01
User entered empty.	Crystal Rowell (b) (4)	27 Aug 2020 16:18:18
	(b) (4)	

US3362124

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:21

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:25:40
User entered empty.	Crystal Rowell (b) (4)	27 Aug 2020 16:18:18
	(b) (4)	

US3362124

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:21

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 16:18:18

US3362124

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:21

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:25:40
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 16:23:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Aug 2020 16:23:47
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	27 Aug 2020 16:23:47
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 16:18:18
User entered empty.	Crystal Rowell (b) (4)	27 Aug 2020 16:18:18
	(b) (4)	

US3362124

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:25:40
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 16:23:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Aug 2020 16:23:47
User entered 'No (N)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	27 Aug 2020 16:23:47
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 16:18:18
User entered empty.	Crystal Rowell (b) (4)	27 Aug 2020 16:18:18
	(b) (4)	

US3362124

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:25:40
User entered '0'	Crystal Rowell (b) (4)	27 Aug 2020 16:18:18
	(b) (4)	

US3362124

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:25:40
User entered '0'	Crystal Rowell (b) (4) (b) (4)	27 Aug 2020 16:18:18

US3362124

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:25:40
User entered '0'	Crystal Rowell (b) (4) (b) (4)	27 Aug 2020 16:18:18

US3362124

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:21

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:25:40
User entered empty.	Crystal Rowell (b) (4)	27 Aug 2020 16:18:18
	(b) (4)	

US3362124

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:21

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:25:40
User entered empty.	Crystal Rowell (b) (4) (b) (4)	27 Aug 2020 16:18:18

US3362124

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:21

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:25:40
User entered empty.	Crystal Rowell (b) (4) (b) (4)	27 Aug 2020 16:18:18

US3362124

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:21

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:25:40
User entered empty.	Crystal Rowell (b) (4) (b) (4)	27 Aug 2020 16:18:18

US3362124

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:25:40
User entered '0'	Crystal Rowell (b) (4)	27 Aug 2020 16:18:18
	(b) (4)	

US3362124

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:25:40
User entered '0'	Crystal Rowell (b) (4) (b) (4)	27 Aug 2020 16:18:18

US3362124

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:25:40
User entered '0'	Crystal Rowell (b) (4) (b) (4)	27 Aug 2020 16:18:18

US3362124

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:25:40
Query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	25 Sep 2020 13:24:42
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	12 Sep 2020 14:00:51
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 16:23:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Aug 2020 16:23:47
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	27 Aug 2020 16:23:47
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	System	27 Aug 2020 16:18:18
User entered empty.	Crystal Rowell (b) (4)	27 Aug 2020 16:18:18
	(b) (4)	

US3362124

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:21

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:25:40
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 16:23:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Aug 2020 16:23:47
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	27 Aug 2020 16:23:47
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	27 Aug 2020 16:18:18
	Crystal Rowell (b) (4)	27 Aug 2020 16:18:18
	(b) (4)	

US3362124

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:21

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:25:40
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	20 Oct 2020 17:51:30
User closed query 'Per CDM re-query: "Dosing discontinuation" form is under "End of Study" folder. Thank you!' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 05:45:19
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'due to SARS COV which is an AE' (Site from System).	Amy Thomassie (b) (4)	16 Oct 2020 16:54:01
	(b) (4)	
Query 'Per CDM re-query: "Dosing discontinuation" form is under "End of Study" folder. Thank you!' answered with 'updated' (Site from DM).	Amy Thomassie (b) (4)	16 Oct 2020 16:52:19
	(b) (4)	
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	16 Oct 2020 16:51:16
User opened query 'Per CDM re-query: "Dosing discontinuation" form is under "End of Study" folder. Thank you!' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 06:22:07
User closed query 'Per CDM: Thank you for your answer. If subject does not receive second vaccine, then please consider entering "Dosing discontinuation" form and also please review this row "Action taken with investigational product" because subject will not receive second vaccine. Thank you!' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 06:22:07

US3362124

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:21

Action taken with investigational product

Audit	User	Time (GMT)
Query 'Per CDM: Thank you for your answer. If subject does not receive second vaccine, then please consider entering "Dosing discontinuation" form and also please review this row "Action taken with investigational product" because subject will not receive second vaccine. Thank you!' answered with 'where is dosing discontinuation form?' (Site from DM).	Crystal Rowell (b) (4)	01 Oct 2020 19:52:08
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Per Query Resolution	Crystal Rowell (b) (4)	01 Oct 2020 19:51:08
User opened query 'Per CDM: Thank you for your answer. If subject does not receive second vaccine, then please consider entering "Dosing discontinuation" form and also please review this row "Action taken with investigational product" because subject will not receive second vaccine. Thank you!' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 10:35:54
User closed query 'Per CDM: Since subject withdrawn from the study, then please kindly consider completing "End of Study" forms. Thank you!' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 10:35:54
Query 'Per CDM: Since subject withdrawn from the study, then please kindly consider completing "End of Study" forms. Thank you!' answered with 'patient is still in study, will not receive vaccine 2' (Site from DM).	Crystal Rowell (b) (4)	30 Sep 2020 15:21:59
User entered 'None (NONE)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	30 Sep 2020 15:21:55
User opened query 'Per CDM: Since subject withdrawn from the study, then please kindly consider completing "End of Study" forms. Thank you!' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 06:03:11
User closed query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 21:39:15

US3362124

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:21

Action taken with investigational product

Audit	User	Time (GMT)
Query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' answered with 'updated' (Site from Safety).	Amy Thomassie (b) (4)	12 Sep 2020 14:01:27
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Amy Thomassie (b) (4)	12 Sep 2020 14:00:51
User opened query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	01 Sep 2020 12:23:04
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 16:23:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Aug 2020 16:23:47
User entered 'None (NONE)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	27 Aug 2020 16:23:47
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 16:18:18
User entered empty.	Crystal Rowell (b) (4)	27 Aug 2020 16:18:18

US3362124

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:21

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:25:40
User entered '0'	Crystal Rowell (b) (4)	27 Aug 2020 16:18:18
	(b) (4)	

US3362124

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:21

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:25:40
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 18:44:06
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'con med #2' (Site from DM).	Amy Thomassie (b) (4)	26 Sep 2020 23:33:43
	(b) (4)	
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 02:16:40
Query 'Per ETRTR: Please update ConMeds CRF page with medication given for COVID, thanks.' canceled (Site from CRA).	(b) (4), (b) (6)	06 Sep 2020 18:40:13
User opened query 'Per ETRTR: Please update ConMeds CRF page with medication given for COVID, thanks.' (Site from CRA).	(b) (4), (b) (6)	29 Aug 2020 16:11:26
User entered 'I'	Crystal Rowell (b) (4)	27 Aug 2020 16:18:18
	(b) (4)	

US3362124

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:21

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:25:40
User entered '0'	Crystal Rowell (b) (4) (b) (4)	27 Aug 2020 16:18:18

US3362124

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:21

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:25:40
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 16:24:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Aug 2020 16:24:01
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Crystal Rowell (b) (4)	27 Aug 2020 16:24:01
Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 16:18:18
User entered empty.	Crystal Rowell (b) (4)	27 Aug 2020 16:18:18
	(b) (4)	

US3362124

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:21

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:25:40
User entered empty.	Crystal Rowell (b) (4) (b) (4)	27 Aug 2020 16:18:18

US3362124

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:21

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:51
User closed query 'PV Query: Please clarify the administration route of famotidine/ibuprofen. Is it oral or topical?' (Site from Safety).	(b) (4), (b) (6)	03 Dec 2020 19:41:29
User closed query 'PV Query: Signs and symptoms from the log were reported as stopping on 24 Aug 2020. The event end date was 18 Sep 2020. Please provide additional symptoms through 18 Sep 2020, or consider updating event stop date to the date of the last signs and symptoms.' (Site from Safety).	(b) (4), (b) (6)	03 Dec 2020 19:41:26
User closed query 'PV Query: Signs and symptoms of the event from the COVID-19 assessment logs were reported as starting on 21 Aug 2020. The event start date was updated to 18 Aug 2020. Please provide signs and symptoms starting from 18 Aug 2020. If unknown or not provided please state as such, or consider updating the event start date to when the signs and symptoms first began.' (Site from Safety).	(b) (4), (b) (6)	03 Dec 2020 19:41:23
Query 'PV Query: Please clarify the administration route of famotidine/ibuprofen. Is it oral or topical?' answered with 'Topical' (Site from Safety).	Alexandra Caillouet (b) (4)	02 Dec 2020 14:34:58
Query 'PV Query: Signs and symptoms from the log were reported as stopping on 24 Aug 2020. The event end date was 18 Sep 2020. Please provide additional symptoms through 18 Sep 2020, or consider updating event stop date to the date of the last signs and symptoms.' answered with 'Symptoms stopped being reported on 24 Aug 2020; however, subject had ongoing positive COVID19 result.' (Site from Safety).	Alexandra Caillouet (b) (4)	02 Dec 2020 14:33:03
Query 'PV Query: Signs and symptoms of the event from the COVID-19 assessment logs were reported as starting on 21 Aug 2020. The event start date was updated to 18 Aug 2020. Please provide signs and symptoms starting from 18 Aug 2020. If unknown or not provided please state as such, or consider updating the event start date to when the signs and symptoms first began.' answered with 'updated' (Site from Safety).	Alexandra Caillouet (b) (4)	02 Dec 2020 14:27:03

US3362124

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:21

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please clarify the administration route of famotidine/ibuprofen. Is it oral or topical?' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 20:14:30
User opened query 'PV Query: Signs and symptoms from the log were reported as stopping on 24 Aug 2020. The event end date was 18 Sep 2020. Please provide additional symptoms through 18 Sep 2020, or consider updating event stop date to the date of the last signs and symptoms.' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 20:14:07
User opened query 'PV Query: Signs and symptoms of the event from the COVID-19 assessment logs were reported as starting on 21 Aug 2020. The event start date was updated to 18 Aug 2020. Please provide signs and symptoms starting from 18 Aug 2020. If unknown or not provided please state as such, or consider updating the event start date to when the signs and symptoms first began.' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 20:13:32
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:25:40
User entered empty; reason for change Data Entry Error	Crystal Rowell (b) (4)	30 Sep 2020 15:21:55
User closed query 'PV Query: Please confirm if the patient had any known exposure to COVID-19.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 21:39:28
User closed query 'PV Query: Please clarify if this is a baseline positive test or if an additional test was performed after 13 Aug 2020. If additional test was performed, please confirm date and result of test.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 21:39:21
User closed query 'PV Query: Please provide results of nasopharyngeal swab from 13 Aug 2020.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 21:39:19
Query 'PV Query: Please confirm if the patient had any known exposure to COVID-19.' answered with 'updated' (Site from Safety).	Amy Thomassie (b) (4)	12 Sep 2020 14:06:44
Query 'PV Query: Please clarify if this is a baseline positive test or if an additional test was performed after 13 Aug 2020. If additional test was performed, please confirm date and result of test.' answered with 'updated' (Site from Safety).	Amy Thomassie (b) (4)	12 Sep 2020 14:06:39

US3362124

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:21

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide results of nasopharyngeal swab from 13 Aug 2020.' answered with 'updated' (Site from Safety).	Amy Thomassie (b) (4)	12 Sep 2020 14:06:35
User entered '13AUG2020 swab not detected. Illness visit swab 21AUG2020 detected. Patient denied known exposure to COVID-19 during phone call 20AUG2020' reason for change: Data Entry Error	Amy Thomassie (b) (4)	12 Sep 2020 14:06:19
Query 'Per ETRTR: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' canceled (Site from CRA).	(b) (4), (b) (6)	06 Sep 2020 18:40:18
Query 'Per ETRTR: COVID + Narrative should describe clinical course of events, dates, times, treatments (include in ConMeds CRF) and any other assessments which help explain the event. Please add as required, thanks.' canceled (Site from CRA).	(b) (4), (b) (6)	06 Sep 2020 18:40:16
User opened query 'PV Query: Please confirm if the patient had any known exposure to COVID-19.' (Site from Safety).	(b) (4), (b) (6)	01 Sep 2020 12:22:55
User opened query 'PV Query: Please clarify if this is a baseline positive test or if an additional test was performed after 13 Aug 2020. If additional test was performed, please confirm date and result of test.' (Site from Safety).	(b) (4), (b) (6)	01 Sep 2020 12:22:45
User opened query 'PV Query: Please provide results of nasopharyngeal swab from 13 Aug 2020.' (Site from Safety).	(b) (4), (b) (6)	01 Sep 2020 12:22:34
User opened query 'Per ETRTR: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from CRA).	(b) (4), (b) (6)	29 Aug 2020 16:05:05

US3362124

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:21

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per ETRTR: COVID + Narrative should describe clinical course of events, dates, times, treatments (include in ConMeds CRF) and any other assessments which help explain the event. Please add as required, thanks.' (Site from CRA). User entered empty.	(b) (4), (b) (6)	29 Aug 2020 16:03:48
	Crystal Rowell (b) (4)	27 Aug 2020 16:18:18

US3362124

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:21

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	27 Aug 2020 16:23:47

US3362124

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:21

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Aug 2020 16:18:18

US3362124

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:21

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:41:58

US3362124

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:21

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:41:58
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:42:07
User signature succeeded.	Jordan Whatley (b) (4)	20 Apr 2021 00:58:01
	(b) (4)	
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Aching joints - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 22:01:37
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 22:01:37
	(b) (4)	
Data point term sent to Coder	System	19 Apr 2021 22:00:42
User entered 'joint aches in several joints'	Alexandra Caillouet	19 Apr 2021 22:00:19
	(b) (4)	

US3362124

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:41:58
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:42:07
User signature succeeded.	Jordan Whatley (b) (4)	20 Apr 2021 00:58:01
	(b) (4)	
User entered 'No (N)'	Alexandra Caillouet	19 Apr 2021 22:00:19
	(b) (4)	

US3362124

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:41:58
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:42:07
User signature succeeded.	Jordan Whatley (b) (4)	20 Apr 2021 00:58:01
	(b) (4)	
User entered 'Yes (Y)'	Alexandra Caillouet	19 Apr 2021 22:00:19
	(b) (4)	

US3362124

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:41:58
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:42:07
User signature succeeded.	Jordan Whatley (b) (4)	20 Apr 2021 00:58:01
User entered 'No (N)'	Alexandra Caillouet (b) (4)	19 Apr 2021 22:00:19

US3362124

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:21

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:41:58
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:42:07
User signature succeeded.	Jordan Whatley (b) (4)	20 Apr 2021 00:58:01
	(b) (4)	
User entered '14 Aug 2020'	Alexandra Caillouet	19 Apr 2021 22:00:19
	(b) (4)	

US3362124

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:21

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:41:58
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:42:07
User signature succeeded.	Jordan Whatley (b) (4)	20 Apr 2021 00:58:01
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Apr 2021 22:03:58
User entered '00:00' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	19 Apr 2021 22:03:58
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Apr 2021 22:00:19
User entered empty.	Alexandra Caillouet (b) (4)	19 Apr 2021 22:00:19

US3362124

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:21

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:41:58
User entered '14 Aug 2020 00:00'	System	19 Apr 2021 22:03:58
User entered empty.	System	19 Apr 2021 22:00:19

US3362124

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:41:58
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:42:07
User signature succeeded.	Jordan Whatley (b) (4)	20 Apr 2021 00:58:01
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 22:03:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Apr 2021 22:03:45
User entered 'No (N)' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	19 Apr 2021 22:03:45
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 22:00:19
User entered empty.	Alexandra Caillouet (b) (4)	19 Apr 2021 22:00:19

US3362124

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:41:58
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:42:07
User signature succeeded.	Jordan Whatley (b) (4)	20 Apr 2021 00:58:01
	(b) (4)	
User entered '23 Aug 2020'	Alexandra Caillouet	19 Apr 2021 22:00:19
	(b) (4)	

US3362124

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:21

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:41:58
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:42:07
User signature succeeded.	Jordan Whatley (b) (4)	20 Apr 2021 00:58:01
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Apr 2021 22:03:58
User entered '00:00' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	19 Apr 2021 22:03:58
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Apr 2021 22:03:45
User entered empty.	Alexandra Caillouet (b) (4)	19 Apr 2021 22:00:19

US3362124

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:21

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:41:58
User entered '23 Aug 2020 00:00'	System	19 Apr 2021 22:03:58
User entered empty.	System	19 Apr 2021 22:00:19

US3362124

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:21

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:41:58
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:42:07
User signature succeeded.	Jordan Whatley (b) (4)	20 Apr 2021 00:58:01
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Alexandra Caillouet	19 Apr 2021 22:00:19
	(b) (4)	

US3362124

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:41:58
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:42:07
User signature succeeded.	Jordan Whatley (b) (4)	20 Apr 2021 00:58:01
	(b) (4)	
User entered 'No (N)'	Alexandra Caillouet	19 Apr 2021 22:00:19
	(b) (4)	

US3362124

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:21

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:41:58
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:42:07
User signature succeeded.	Jordan Whatley (b) (4)	20 Apr 2021 00:58:01
	(b) (4)	
User entered '0'	Alexandra Caillouet	19 Apr 2021 22:00:19
	(b) (4)	

US3362124

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:21

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:41:58
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:42:07
User signature succeeded.	Jordan Whatley (b) (4)	20 Apr 2021 00:58:01
	(b) (4)	
User entered '0'	Alexandra Caillouet	19 Apr 2021 22:00:19
	(b) (4)	

US3362124

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:41:58
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:42:07
User signature succeeded.	Jordan Whatley (b) (4)	20 Apr 2021 00:58:01
	(b) (4)	
User entered '0'	Alexandra Caillouet	19 Apr 2021 22:00:19
	(b) (4)	

US3362124

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:21

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:41:58
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:42:07
User signature succeeded.	Jordan Whatley (b) (4)	20 Apr 2021 00:58:01
	(b) (4)	
User entered empty.	Alexandra Caillouet	19 Apr 2021 22:00:19
	(b) (4)	

US3362124

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:21

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:41:58
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:42:07
User signature succeeded.	Jordan Whatley (b) (4)	20 Apr 2021 00:58:01
User entered empty.	Alexandra Caillouet (b) (4)	19 Apr 2021 22:00:19

US3362124

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:21

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:41:58
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:42:07
User signature succeeded.	Jordan Whatley (b) (4)	20 Apr 2021 00:58:01
	(b) (4)	
User entered empty.	Alexandra Caillouet	19 Apr 2021 22:00:19
	(b) (4)	

US3362124

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:21

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:41:58
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:42:07
User signature succeeded.	Jordan Whatley (b) (4)	20 Apr 2021 00:58:01
	(b) (4)	
User entered empty.	Alexandra Caillouet	19 Apr 2021 22:00:19
	(b) (4)	

US3362124

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:41:58
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:42:07
User signature succeeded.	Jordan Whatley (b) (4)	20 Apr 2021 00:58:01
	(b) (4)	
User entered '0'	Alexandra Caillouet	19 Apr 2021 22:00:19
	(b) (4)	

US3362124

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:41:58
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:42:07
User signature succeeded.	Jordan Whatley (b) (4)	20 Apr 2021 00:58:01
	(b) (4)	
User entered '0'	Alexandra Caillouet	19 Apr 2021 22:00:19
	(b) (4)	

US3362124

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:21

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:41:58
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:42:07
User signature succeeded.	Jordan Whatley (b) (4)	20 Apr 2021 00:58:01
	(b) (4)	
User entered '0'	Alexandra Caillouet	19 Apr 2021 22:00:19
	(b) (4)	

US3362124

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:41:58
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 19:42:07
Signature has been broken.		20 Apr 2021 16:27:49
User entered 'Related (RELATED)' reason for change: Data Entry Error		20 Apr 2021 16:27:49
User signature succeeded.	Jordan Whatley (b) (4)	20 Apr 2021 00:58:01
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Alexandra Caillouet	19 Apr 2021 22:00:19
	(b) (4)	

US3362124

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:21

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:41:58
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:42:07
User signature succeeded.	Jordan Whatley (b) (4)	20 Apr 2021 00:58:01
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Alexandra Caillouet	19 Apr 2021 22:00:19
	(b) (4)	

US3362124

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:21

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:41:58
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:42:07
User signature succeeded.	Jordan Whatley (b) (4)	20 Apr 2021 00:58:01
	(b) (4)	
User entered 'None (NONE)'	Alexandra Caillouet	19 Apr 2021 22:00:19
	(b) (4)	

US3362124

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:21

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:41:58
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:42:07
User signature succeeded.	Jordan Whatley (b) (4)	20 Apr 2021 00:58:01
	(b) (4)	
User entered 'l'	Alexandra Caillouet	19 Apr 2021 22:00:19
	(b) (4)	

US3362124

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:21

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:41:58
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:42:07
User signature succeeded.	Jordan Whatley (b) (4)	20 Apr 2021 00:58:01
	(b) (4)	
User entered '0'	Alexandra Caillouet	19 Apr 2021 22:00:19
	(b) (4)	

US3362124

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:21

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:41:58
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:42:07
User signature succeeded.	Jordan Whatley (b) (4)	20 Apr 2021 00:58:01
	(b) (4)	
User entered '0'	Alexandra Caillouet	19 Apr 2021 22:00:19
	(b) (4)	

US3362124

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:21

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:41:58
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:42:07
User signature succeeded.	Jordan Whatley (b) (4)	20 Apr 2021 00:58:01
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Alexandra Caillouet	19 Apr 2021 22:00:19
	(b) (4)	

US3362124

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:21

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:41:58
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:42:07
User signature succeeded.	Jordan Whatley (b) (4)	20 Apr 2021 00:58:01
	(b) (4)	
User entered empty.	Alexandra Caillouet	19 Apr 2021 22:00:19
	(b) (4)	

US3362124

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:21

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:41:58
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:42:07
User signature succeeded.	Jordan Whatley (b) (4)	20 Apr 2021 00:58:01
	(b) (4)	
User entered empty.	Alexandra Caillouet	19 Apr 2021 22:00:19
	(b) (4)	

US3362124

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:21

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:41:58
User entered '0'	System	19 Apr 2021 22:00:19

US3362124

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:21

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:41:58
User entered '0'	System	19 Apr 2021 22:00:19

US3362124

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:21

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:41:58

US3362124

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:36:21

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:26:42
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:39
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:26:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 21:25:33

US3362124

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:36:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:40:50
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Aug 2020 21:27:17
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Aug 2020 21:27:17
	(b) (4)	
Data point term sent to Coder	System	13 Aug 2020 21:27:00
User entered 'flonase'	(b) (4), (b) (6)	13 Aug 2020 21:26:04

US3362124

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:36:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:40:50
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 21:26:04

US3362124

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:36:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:40:50
User entered 'allergic rhinitis'	(b) (4), (b) (6)	13 Aug 2020 21:26:04

US3362124

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:36:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:40:50
User entered '50'	(b) (4), (b) (6)	13 Aug 2020 21:26:04

US3362124

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:36:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:40:50
User entered 'ug (ug)'	(b) (4), (b) (6)	13 Aug 2020 21:26:04

US3362124

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:36:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:40:50
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 21:26:04

US3362124

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:36:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:40:50
User entered 'as needed (PRN)'	(b) (4), (b) (6)	13 Aug 2020 21:26:04

US3362124

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:36:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:40:50
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 21:26:04

US3362124

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:36:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:40:50
User entered 'Nasal (NASAL)'	(b) (4), (b) (6)	13 Aug 2020 21:26:04

US3362124

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:36:21

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:40:50
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 21:26:04

US3362124

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:36:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:40:50
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	15 Aug 2020 18:21:14
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 21:26:04
User entered 'un UNK 2019'	(b) (4), (b) (6)	13 Aug 2020 21:26:04

US3362124

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:36:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:40:50
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 21:26:04

US3362124

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:36:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:40:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 21:26:04

US3362124

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:36:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:40:50
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 21:26:04

US3362124

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:36:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:40:50
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 21:26:04

US3362124

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:36:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 21:26:04

US3362124

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:36:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 21:26:04

US3362124

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:36:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 21:26:04

US3362124

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:36:21

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:24:25
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:39
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:40:50
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: FAMOTIDINE;IBUPROFEN, PRODUCTSYNONYM: DUEXIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 11:44:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 11:44:45
Data point term sent to Coder	System	16 Oct 2020 15:46:14
Coding entries removed.	(b) (4), (b) (6)	16 Oct 2020 15:45:24
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: FAMOTIDINE;IBUPROFEN, PRODUCTSYNONYM: DUEXIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Sep 2020 13:16:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Sep 2020 13:16:45
Data point term sent to Coder	System	03 Sep 2020 18:10:27
User entered 'duexis topical'	(b) (4), (b) (6)	03 Sep 2020 18:09:47

US3362124

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:36:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:24:25
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:39
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:40:50
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 18:09:47

US3362124

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:36:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:24:25
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:40:50
User closed query 'Per DM CLR: Please confirm if this is related to AE#1 SARS COV 2 INFECTION. If yes, please update indication to match AE terms. Otherwise, please add an AE entry for this indication if not related to AE#1. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 09:41:25
Query 'Per DM CLR: Please confirm if this is related to AE#1 SARS COV 2 INFECTION. If yes, please update indication to match AE terms. Otherwise, please add an AE entry for this indication if not related to AE#1. Update as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 15:45:34
User entered 'sars-cov 2 infection' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 15:45:24
User opened query 'Per DM CLR: Please confirm if this is related to AE#1 SARS COV 2 INFECTION. If yes, please update indication to match AE terms. Otherwise, please add an AE entry for this indication if not related to AE#1. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 12:55:20
User entered 'body aches associated with upper respiratory infection'	(b) (4), (b) (6)	03 Sep 2020 18:09:47

US3362124

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:36:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:24:25
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:39
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:40:50
User entered 'l'	(b) (4), (b) (6)	03 Sep 2020 18:09:47

US3362124

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:36:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:24:25
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:39
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:40:50
User entered 'Other (OTHER)'	(b) (4), (b) (6)	03 Sep 2020 18:09:47

US3362124

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:36:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:24:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:13:38
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:39
DataPoint Un-verified.	(b) (4)	02 Dec 2020 14:34:35
User entered 'APPLICATION' reason for change:	Alexandra Caillouet	02 Dec 2020 14:34:35
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:40:50
User entered 'topical application'	(b) (4), (b) (6)	03 Sep 2020 18:09:47

US3362124

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:36:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:24:25
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:39
DataPoint Verified.	(b) (4)	04 Nov 2020 21:40:50
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 18:10:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 18:10:01
User entered 'once (ONCE)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 18:10:01
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 18:09:47
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 18:09:47

US3362124

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:36:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:24:25
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:39
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:40:50
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 18:09:47

US3362124

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:36:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:24:25
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:39
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:40:50
User entered 'Topical (TOPICAL)'	(b) (4), (b) (6)	03 Sep 2020 18:09:47

US3362124

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:36:21

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:24:25
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:39
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:40:50
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 18:09:47

US3362124

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:24:25
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:39
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:40:50
User entered '21 Aug 2020'	(b) (4), (b) (6)	03 Sep 2020 18:09:47

US3362124

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:36:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:24:25
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:39
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:40:50
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 18:09:47

US3362124

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:36:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:24:25
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:39
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:40:50
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 18:09:47

US3362124

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:36:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:24:25
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:39
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:40:50
User entered '21 Aug 2020'	(b) (4), (b) (6)	03 Sep 2020 18:09:47

US3362124

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:36:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:24:25
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:39
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:40:50
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 18:09:47

US3362124

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:36:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:24:25
User entered empty.	System	03 Sep 2020 18:09:47

US3362124

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:36:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:24:25
User entered empty.	System	03 Sep 2020 18:09:47

US3362124

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:36:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:24:25
User entered empty.	System	03 Sep 2020 18:09:47

US3362124

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:36:21

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:41:24
User entered 'No (N)'	(b) (4), (b) (6)	29 Aug 2020 13:32:20

US3362124

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:36:21

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:35
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:12:09
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 19:54:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Oct 2020 19:54:29
User entered 'Visit 2 Day 29 (VISIT2)' reason for change: Data Entry Error	Crystal Rowell (b) (4) (b) (4)	01 Oct 2020 19:54:29
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 19:54:05
User entered empty.	Crystal Rowell (b) (4) (b) (4)	01 Oct 2020 19:54:05

US3362124

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:36:21

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:35
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:12:09
User closed query 'There are no selections for Case Report Form. Please review and reconcile.' (Site from System).	System	01 Oct 2020 19:54:29
Query 'There are no selections for Case Report Form. Please review and reconcile.' answered by data change (Site from System).		01 Oct 2020 19:54:29
User entered '1' reason for change: Data Entry Error	Crystal Rowell (b) (4)	01 Oct 2020 19:54:29
User opened query 'There are no selections for Case Report Form. Please review and reconcile.' (Site from System).	(b) (4) System	01 Oct 2020 19:54:05
User entered '0'	Crystal Rowell (b) (4) (b) (4)	01 Oct 2020 19:54:05

US3362124

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:36:21

[Demographics](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:35
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:12:09
User entered '0'	Crystal Rowell (b) (4)	01 Oct 2020 19:54:05

US3362124

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:36:21

[Enrollment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:35
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:12:09
User entered '0'	Crystal Rowell (b) (4)	01 Oct 2020 19:54:05

US3362124

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:36:21

[Inclusion/Exclusion Criteria Summary](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:35
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:12:09
User entered '0'	Crystal Rowell (b) (4)	01 Oct 2020 19:54:05

US3362124

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:36:21

[Inclusion/Exclusion Criteria](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:35
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:12:09
User entered '0'	Crystal Rowell (b) (4)	01 Oct 2020 19:54:05

US3362124

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:36:21

[Medical History Summary](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:35
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:12:09
User entered '0'	Crystal Rowell (b) (4)	01 Oct 2020 19:54:05

US3362124

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:36:21

[Medical History](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:35
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:12:09
User entered '0'	Crystal Rowell (b) (4)	01 Oct 2020 19:54:05

US3362124

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:36:21

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:35
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:12:09
User entered '0'	Crystal Rowell (b) (4)	01 Oct 2020 19:54:05

US3362124

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:36:21

[Vital Signs - Dosing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:35
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:12:09
User entered '0'	Crystal Rowell (b) (4)	01 Oct 2020 19:54:05

US3362124

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:36:21

[Physical Examination](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:35
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:12:09
User entered '0'	Crystal Rowell (b) (4)	01 Oct 2020 19:54:05

US3362124

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:36:21

[Central Laboratory - Nasopharyngeal Swab](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:35
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:12:09
User entered '0'	Crystal Rowell (b) (4)	01 Oct 2020 19:54:05

US3362124

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:36:21

[Childbearing Potential](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:35
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:12:09
User entered '0'	Crystal Rowell (b) (4)	01 Oct 2020 19:54:05

US3362124

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:36:21

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:35
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:12:09
User entered '0'	Crystal Rowell (b) (4)	01 Oct 2020 19:54:05

US3362124

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:36:21

[Randomization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:35
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:12:09
User entered '0'	Crystal Rowell (b) (4)	01 Oct 2020 19:54:05

US3362124

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:36:21

[Exposure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:35
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:12:09
User entered '0'	Crystal Rowell (b) (4)	01 Oct 2020 19:54:05

US3362124

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:36:21

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:35
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:12:09
User entered '0'	Crystal Rowell (b) (4)	01 Oct 2020 19:54:05

US3362124

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:36:21

[Saliva Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:35
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:12:09
User entered '0'	Crystal Rowell (b) (4)	01 Oct 2020 19:54:05

US3362124

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:36:21

[COVID Diagnostic Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:35
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:12:09
User entered '0'	Crystal Rowell (b) (4)	01 Oct 2020 19:54:05

US3362124

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:36:21

[Symptom Log](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:35
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:12:09
User entered '0'	Crystal Rowell (b) (4)	01 Oct 2020 19:54:05

US3362124

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:36:21

[Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:35
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:12:09
User entered '0'	Crystal Rowell (b) (4)	01 Oct 2020 19:54:05

US3362124

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:36:21

[COVID-19 Severity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:35
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:12:09
User entered '0'	Crystal Rowell (b) (4)	01 Oct 2020 19:54:05

US3362124

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:36:21

[COVID-19 Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:35
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:12:09
User entered '0'	Crystal Rowell (b) (4)	01 Oct 2020 19:54:05

US3362124

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:36:21

[Risk of Exposure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:35
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:12:09
User entered '0'	Crystal Rowell (b) (4)	01 Oct 2020 19:54:05

US3362124

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:36:21

[Safety Call](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:35
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:12:09
User entered '0'	Crystal Rowell (b) (4)	01 Oct 2020 19:54:05

US3362124

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:36:21

[Dosing Discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:35
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:12:09
User entered '0'	Crystal Rowell (b) (4)	01 Oct 2020 19:54:05

US3362124

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:36:21

[End of Study / Study Discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:35
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:12:09
User entered '0'	Crystal Rowell (b) (4)	01 Oct 2020 19:54:05

US3362124

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:36:21

[All](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:35
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:12:09
User entered '0'	Crystal Rowell (b) (4)	01 Oct 2020 19:54:05

US3362124

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:36:21

[Date of missed or out of window visit or assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:35
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:12:09
User entered '17 Sep 2020'	Crystal Rowell (b) (4)	01 Oct 2020 19:54:05

US3362124

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:36:21

[Inclusion criteria not met/Exclusion criteria met](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:35
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:12:09
User entered '0'	Crystal Rowell (b) (4)	01 Oct 2020 19:54:05

US3362124

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:36:21

[Study Treatment not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:35
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:12:09
User entered 'I'	Crystal Rowell (b) (4)	01 Oct 2020 19:54:05

US3362124

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:36:21

[Missed Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:35
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:12:09
User entered '0'	Crystal Rowell (b) (4)	01 Oct 2020 19:54:05

US3362124

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:36:21

[Missed Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:35
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:12:09
User entered '0'	Crystal Rowell (b) (4)	01 Oct 2020 19:54:05

US3362124

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:36:21

[Visit performed out of window](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:35
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:12:09
User entered '0'	Crystal Rowell (b) (4)	01 Oct 2020 19:54:05

US3362124

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:36:21

[Assessment performed out of window](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:35
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:12:09
User entered '0'	Crystal Rowell (b) (4)	01 Oct 2020 19:54:05

US3362124

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:36:21

[Scheduled clinical visit performed as home visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:35
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:12:09
User entered '0'	Crystal Rowell (b) (4)	01 Oct 2020 19:54:05

US3362124

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:36:21

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:35
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:12:09
User entered '0'	Crystal Rowell (b) (4)	01 Oct 2020 19:54:05

US3362124

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:36:21

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:35
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:12:09
User entered empty.	Crystal Rowell (b) (4)	01 Oct 2020 19:54:05

US3362124

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:36:21

[Clinical site closed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:35
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:12:09
User entered '0'	Crystal Rowell (b) (4)	01 Oct 2020 19:54:05

US3362124

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:36:21

[Travel restrictions](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:35
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:12:09
User entered '0'	Crystal Rowell (b) (4)	01 Oct 2020 19:54:05

US3362124

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:36:21

[Quarantine due to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:35
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:12:09
User entered '0'	Crystal Rowell (b) (4)	01 Oct 2020 19:54:05

US3362124

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:36:21

[Possible exposure to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:35
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:12:09
User entered '0'	Crystal Rowell (b) (4)	01 Oct 2020 19:54:05

US3362124

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:36:21

[Exposure to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:35
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:12:09
User entered '0'	Crystal Rowell (b) (4)	01 Oct 2020 19:54:05

US3362124

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:36:21

[Presumption / confirmed COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:35
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:12:09
User entered 'I'	Crystal Rowell (b) (4)	01 Oct 2020 19:54:05

US3362124

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:36:21

[Symptoms of COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:35
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:12:09
User entered '0'	Crystal Rowell (b) (4)	01 Oct 2020 19:54:05

US3362124

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:36:21

[Sponsor hold due to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:35
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:12:09
User entered '0'	Crystal Rowell (b) (4)	01 Oct 2020 19:54:05

US3362124

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:36:21

[Participant decision](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:35
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:12:09
User entered '0'	Crystal Rowell (b) (4)	01 Oct 2020 19:54:05

US3362124

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:36:21

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:54:34
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:14:03
User closed query 'Per CDM: Please be aware that COVID-19 test and AE start date are 21AUg2020, however dosing discontinuation is marked as 18AUG2020. Please be aware that discontinuation date cannot be before AE start date. Please review and update or clarify otherwise. Thank you!' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 07:54:25
Query 'Per CDM: Please be aware that COVID-19 test and AE start date are 21AUg2020, however dosing discontinuation is marked as 18AUG2020. Please be aware that discontinuation date cannot be before AE start date. Please review and update or clarify otherwise. Thank you!' answered with 'updated' (Site from DM).	Amy Thomassie (b) (4)	20 Oct 2020 10:51:47
User entered '21 Aug 2020' reason for change: Data Entry Error	(b) (4)	20 Oct 2020 10:51:40
User opened query 'Per CDM: Please be aware that COVID-19 test and AE start date are 21AUg2020, however dosing discontinuation is marked as 18AUG2020. Please be aware that discontinuation date cannot be before AE start date. Please review and update or clarify otherwise. Thank you!' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 05:44:56
User entered '18 Aug 2020'	Amy Thomassie (b) (4)	16 Oct 2020 16:51:16

US3362124

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:36:21

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:54:34
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:14:03
User closed query 'Per CDM: Primary reason for dosing discontinuation is recorded as 'Due to SARS-COV-2',However, no data is recorded on 'End of Study / Study Discontinuation' form. Kindly verify and consider to update the necessary eCRFs required else clarify.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 05:17:34
Query 'Per CDM: Primary reason for dosing discontinuation is recorded as 'Due to SARS-COV-2',However, no data is recorded on 'End of Study / Study Discontinuation' form. Kindly verify and consider to update the necessary eCRFs required else clarify.' answered with 'this is not completed because the subject is not discontinuing from the entire study, he is still completing safety follow ups, per ecrf guidelines end of study is not used until end of ALL study procedures' (Site from DM).	Crystal Rowell (b) (4) (b) (4)	21 Oct 2020 21:19:12
User opened query 'Per CDM: Primary reason for dosing discontinuation is recorded as 'Due to SARS-COV-2',However, no data is recorded on 'End of Study / Study Discontinuation' form. Kindly verify and consider to update the necessary eCRFs required else clarify.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 07:21:17
User entered 'Due to SARS-COV-2 (COVID)'	Amy Thomassie (b) (4) (b) (4)	16 Oct 2020 16:51:16

US3362124

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:54:34
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:14:03
User entered empty.	Amy Thomassie (b) (4)	16 Oct 2020 16:51:16

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered		
'USA-US112-2020-MRNA-1273-P301000001'	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered 'No (N)'	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered 'No (N)'	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered 'No (N)'	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered 'No (N)'	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered 'No (N)'	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered 'No (N)'	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered 'No (N)'	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 21:37:09
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Un-reviewed for Safety.	System	14 Sep 2020 21:40:01
User entered 'Jordan'	System	14 Sep 2020 21:40:01
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered (b) (6)	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 21:37:09
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Un-reviewed for Safety.	System	14 Sep 2020 21:40:01
User entered 'Whatley'	System	14 Sep 2020 21:40:01
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered (b) (6)	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 21:37:09
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Un-reviewed for Safety.	System	14 Sep 2020 21:40:01
User entered '5326 O'donovan dr'	System	14 Sep 2020 21:40:01
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered (b) (6)	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 21:37:09
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Un-reviewed for Safety.	System	14 Sep 2020 21:40:01
User entered 'baton rouge'	System	14 Sep 2020 21:40:01
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered (b) (6)	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 21:37:09
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Un-reviewed for Safety.	System	14 Sep 2020 21:40:01
User entered empty.	System	14 Sep 2020 21:40:01
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered (b) (6)	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 21:37:09
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Un-reviewed for Safety.	System	14 Sep 2020 21:40:01
User entered '70808'	System	14 Sep 2020 21:40:01
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered (b) (6)	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:08:43
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 06:58:11
Reviewed for Safety.	(b) (4), (b) (6)	14 Sep 2020 21:39:47
User entered 'US' (non-conformant).	System	27 Aug 2020 17:16:25

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	03 Dec 2020 19:18:01
User entered '3'	System	19 Nov 2020 21:37:26
User entered '2'	System	14 Sep 2020 21:40:01
User entered '1'	System	27 Aug 2020 17:16:25

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered		
'USA-US112-2020-MRNA-1273-P301000001'	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered 'No (N)'	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered 'No (N)'	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered 'No (N)'	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered 'No (N)'	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered 'No (N)'	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered 'No (N)'	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered 'No (N)'	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 21:37:09
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Un-reviewed for Safety.	System	14 Sep 2020 21:40:01
User entered 'Jordan'	System	14 Sep 2020 21:40:01
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered (b) (6)	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 21:37:09
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Un-reviewed for Safety.	System	14 Sep 2020 21:40:01
User entered 'Whatley'	System	14 Sep 2020 21:40:01
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered (b) (6)	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 21:37:09
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Un-reviewed for Safety.	System	14 Sep 2020 21:40:01
User entered '5326 O'donovan dr'	System	14 Sep 2020 21:40:01
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered (b) (6)	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 21:37:09
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Un-reviewed for Safety.	System	14 Sep 2020 21:40:01
User entered 'baton rouge'	System	14 Sep 2020 21:40:01
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered (b) (6)	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 21:37:09
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Un-reviewed for Safety.	System	14 Sep 2020 21:40:01
User entered empty.	System	14 Sep 2020 21:40:01
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered (b) (6)	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 21:37:09
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Un-reviewed for Safety.	System	14 Sep 2020 21:40:01
User entered '70808'	System	14 Sep 2020 21:40:01
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered (b) (6)	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:08:43
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 06:58:11
Reviewed for Safety.	(b) (4), (b) (6)	14 Sep 2020 21:39:47
User entered 'US' (non-conformant).	System	27 Aug 2020 17:16:25

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	03 Dec 2020 19:18:01
User entered '3'	System	19 Nov 2020 21:37:26
User entered '2'	System	14 Sep 2020 21:40:01
User entered '1'	System	27 Aug 2020 17:16:25

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:36:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:08:43
User entered '27/Aug/2020 13:16'	System	27 Aug 2020 17:16:25

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:36:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:08:43
Reviewed for Safety.		14 Sep 2020 21:39:47
User entered 'I'		27 Aug 2020 17:16:25

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered		
'USA-US112-2020-MRNA-1273-P301000001'	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered 'No (N)'	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered 'No (N)'	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered 'No (N)'	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered 'No (N)'	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered 'No (N)'	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered 'No (N)'	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered 'No (N)'	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 21:37:09
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Un-reviewed for Safety.	System	14 Sep 2020 21:40:01
User entered 'Jordan'	System	14 Sep 2020 21:40:01
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered (b) (6)	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 21:37:09
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Un-reviewed for Safety.	System	14 Sep 2020 21:40:01
User entered 'Whatley'	System	14 Sep 2020 21:40:01
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered (b) (6)	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 21:37:09
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Un-reviewed for Safety.	System	14 Sep 2020 21:40:01
User entered '5326 O'donovan dr'	System	14 Sep 2020 21:40:01
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered (b) (6)	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 21:37:09
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Un-reviewed for Safety.	System	14 Sep 2020 21:40:01
User entered 'baton rouge'	System	14 Sep 2020 21:40:01
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered (b) (6)	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 21:37:09
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Un-reviewed for Safety.	System	14 Sep 2020 21:40:01
User entered empty.	System	14 Sep 2020 21:40:01
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered (b) (6)	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 21:37:09
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Un-reviewed for Safety.	System	14 Sep 2020 21:40:01
User entered '70808'	System	14 Sep 2020 21:40:01
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered (b) (6)	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 06:58:11
Reviewed for Safety.	(b) (4), (b) (6)	14 Sep 2020 21:39:47
User entered 'US' (non-conformant).	System	27 Aug 2020 17:16:25

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	03 Dec 2020 19:18:01
User entered '3'	System	19 Nov 2020 21:37:26
User entered '2'	System	14 Sep 2020 21:40:01
User entered '1'	System	27 Aug 2020 17:16:25

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:36:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:08:43
User entered '14/Sep/2020 17:39'	System	14 Sep 2020 21:40:01

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:36:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
Reviewed for Safety.	(b) (4)	19 Nov 2020 21:37:09
	(b) (4), (b) (6)	04 Nov 2020 21:08:43
DataPoint Verified.		14 Sep 2020 21:40:01
User entered '1'		

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered		
'USA-US112-2020-MRNA-1273-P301000001'	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered 'No (N)'	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered 'No (N)'	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered 'No (N)'	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered 'No (N)'	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered 'No (N)'	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered 'No (N)'	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered 'No (N)'	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 21:37:09
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Un-reviewed for Safety.	System	14 Sep 2020 21:40:01
User entered 'Jordan'	System	14 Sep 2020 21:40:01
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered (b) (6)	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 21:37:09
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Un-reviewed for Safety.	System	14 Sep 2020 21:40:01
User entered 'Whatley'	System	14 Sep 2020 21:40:01
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered (b) (6)	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 21:37:09
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Un-reviewed for Safety.	System	14 Sep 2020 21:40:01
User entered '5326 O'donovan dr'	System	14 Sep 2020 21:40:01
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered (b) (6)	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 21:37:09
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Un-reviewed for Safety.	System	14 Sep 2020 21:40:01
User entered 'baton rouge'	System	14 Sep 2020 21:40:01
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered (b) (6)	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 21:37:09
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Un-reviewed for Safety.	System	14 Sep 2020 21:40:01
User entered empty.	System	14 Sep 2020 21:40:01
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered (b) (6)	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 21:37:09
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Un-reviewed for Safety.	System	14 Sep 2020 21:40:01
User entered '70808'	System	14 Sep 2020 21:40:01
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered (b) (6)	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:08:43
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 06:58:11
Reviewed for Safety.	(b) (4), (b) (6)	14 Sep 2020 21:39:47
User entered 'US' (non-conformant).	System	27 Aug 2020 17:16:25

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	03 Dec 2020 19:18:01
User entered '3'	System	19 Nov 2020 21:37:26
User entered '2'	System	14 Sep 2020 21:40:01
User entered '1'	System	27 Aug 2020 17:16:25

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:36:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:12:27
User entered '19/Nov/2020 16:37'	System	19 Nov 2020 21:37:26

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:36:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:12:27
Reviewed for Safety.		03 Dec 2020 19:17:42
User entered '1'		19 Nov 2020 21:37:26

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered		
'USA-US112-2020-MRNA-1273-P301000001'	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered 'No (N)'	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered 'No (N)'	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered 'No (N)'	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered 'No (N)'	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered 'No (N)'	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered 'No (N)'	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered 'No (N)'	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 21:37:09
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Un-reviewed for Safety.	System	14 Sep 2020 21:40:01
User entered 'Jordan'	System	14 Sep 2020 21:40:01
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered (b) (6)	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 21:37:09
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Un-reviewed for Safety.	System	14 Sep 2020 21:40:01
User entered 'Whatley'	System	14 Sep 2020 21:40:01
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered (b) (6)	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 21:37:09
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Un-reviewed for Safety.	System	14 Sep 2020 21:40:01
User entered '5326 O'donovan dr'	System	14 Sep 2020 21:40:01
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered (b) (6)	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 21:37:09
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Un-reviewed for Safety.	System	14 Sep 2020 21:40:01
User entered 'baton rouge'	System	14 Sep 2020 21:40:01
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered (b) (6)	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 21:37:09
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Un-reviewed for Safety.	System	14 Sep 2020 21:40:01
User entered empty.	System	14 Sep 2020 21:40:01
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered (b) (6)	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 21:37:09
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:43
Un-reviewed for Safety.	System	14 Sep 2020 21:40:01
User entered '70808'	System	14 Sep 2020 21:40:01
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 17:16:17
User entered (b) (6)	System	27 Aug 2020 17:14:35

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:08:43
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 06:58:11
Reviewed for Safety.	(b) (4), (b) (6)	14 Sep 2020 21:39:47
User entered 'US' (non-conformant).	System	27 Aug 2020 17:16:25

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	03 Dec 2020 19:18:01
User entered '3'	System	19 Nov 2020 21:37:26
User entered '2'	System	14 Sep 2020 21:40:01
User entered '1'	System	27 Aug 2020 17:16:25

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 11 Aug 2021 22:36:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:12:27
User entered '03/Dec/2020 19:17'	System	03 Dec 2020 19:18:01

US3362124

Folder: SAE USA-US112-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 11 Aug 2021 22:36:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:12:27
User entered 'I'	(b) (4), (b) (6)	03 Dec 2020 19:18:01