

US3362125 (Prod: Meridian Clinical Research-(Baton Rouge, Louisiana) - Platinum - PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:17:16

All time stamps listed in this document are displayed in GMT

US3362125

Form: Participant Creation

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

[Participant ID](#)

US3362125

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

US3362125

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 10 Apr 2021 00:18:00

Generated On: 09 Jun 2021 17:17:16

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

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 10 Apr 2021 00:18:00

Generated On: 09 Jun 2021 17:17:16

Date of Birth (MMM yyyy)	(b) (6) 1953
Age	66
Age Units	YEARS
Age (Derived)	66
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 10 Apr 2021 00:18:00

Generated On: 09 Jun 2021 17:17:16

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 10 Apr 2021 00:18:00

Generated On: 09 Jun 2021 17:17:16

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 10 Apr 2021 00:18:00

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 10 Apr 2021 00:18:00

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Condition	ESSENTIAL HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Start Year (derived)	2008
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 10 Apr 2021 00:18:00

Generated On: 09 Jun 2021 17:17:16

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Start Year (derived)	2008
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 10 Apr 2021 00:18:00

Generated On: 09 Jun 2021 17:17:16

Condition	DERMATITIS GENERALIZED
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 10 Apr 2021 00:18:00

Generated On: 09 Jun 2021 17:17:16

Condition	ATRIAL FLUTTER
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 10 Apr 2021 00:18:00

Generated On: 09 Jun 2021 17:17:16

Condition	ATRIAL FLUTTER ABLATION
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 10 Apr 2021 00:18:00

Generated On: 09 Jun 2021 17:17:16

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 10 Apr 2021 00:18:00

Generated On: 09 Jun 2021 17:17:16

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>)	10:40 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 10:40
Height (<i>xxx.x</i>)	183 cm
Weight (<i>xxx.x</i>)	96.9 kg
BMI (<i>xxx.x</i>)	28.93487 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 10 Apr 2021 00:18:00

Generated On: 09 Jun 2021 17:17:16

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 10 Apr 2021 00:18:00

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☒ No ☐

Specify

(b) (6) MEMBER, FREQUENT GATHERINGS. BABYSITTING GRANDKIDS

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 10 Apr 2021 00:18:00

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 14:04:33

Generated On: 09 Jun 2021 17:17:16

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

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 20 Feb 2021 14:04:33

Generated On: 09 Jun 2021 17:17:16

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

What was the participant's randomization number? 185749

In what Cohort was the participant enrolled?
 >=18 and <65 years and not at risk ☐
 >=18 and <65 years and at risk ☐
 >=65 years ☒

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes ☐ No ☒

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes ☐ No ☒

Severe obesity (body mass index > or = 40kg/m2) Yes ☐ No ☒

Diabetes (Type I, Type 2, or gestational) Yes ☐ No ☒

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 20 Feb 2021 14:04:33

Generated On: 09 Jun 2021 17:17:16

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 20 Feb 2021 14:04:33

Generated On: 09 Jun 2021 17:17:16

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)	10:40 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 10:40
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	163 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	97 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Feb 2021 14:04:33

Generated On: 09 Jun 2021 17:17:16

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)	12:05 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 12:05
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)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	150 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 14:04:33

Generated On: 09 Jun 2021 17:17:16

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.

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 20 Feb 2021 14:04:33

Generated On: 09 Jun 2021 17:17:16

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) 11:35 (24 HR)

Treatment Date and Time (derived) 13 AUG 2020 11:35

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 14:04:33

Generated On: 09 Jun 2021 17:17:16

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	13 AUG 2020
Collection time (<i>00:00-23:59</i>)	11:07 (24 HR)
Collection date and time (derived)	13 AUG 2020 11:07

US3362125

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 14:04:32

Generated On: 09 Jun 2021 17:17:16

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	10:56	13 AUG 2020 10:56
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:04:33

Generated On: 09 Jun 2021 17:17:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:17:16

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 12:06

PC Open Date & Time

13 AUG 2020 11:55

PC Close Date & Time

13 AUG 2020 14:25

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.7 °F

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

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

PC Time Stamp	13 AUG 2020 20:52
PC Open Date & Time	13 AUG 2020 15:20
PC Close Date & Time	14 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:17:16

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

97.8 °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

14 AUG 2020 21:14

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

15 AUG 2020 20:27

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3362125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 20:11

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3362125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 AUG 2020 20:36

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3362125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:17:16

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 AUG 2020 21:00

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3362125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 AUG 2020 22:26

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 12:07

PC Open Date & Time

13 AUG 2020 11:55

PC Close Date & Time

13 AUG 2020 14:25

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:17:16

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 20:53

PC Open Date & Time

13 AUG 2020 15:20

PC Close Date & Time

14 AUG 2020 11:59

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:17:16

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 21:15

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:17:16

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 20:28

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:17:16

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 20:12

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:17:16

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 20:36

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:17:16

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 21:00

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT	DAY 7
Please record - PAIN AT INJECTION SITE.	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
Is there any REDNESS AT INJECTION SITE?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Is there any SWELLING/HARDNESS AT INJECTION SITE?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Please record - UNDERARM GLAND SWELLING OR TENDERNESS.	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
PC Time Stamp	19 AUG 2020 22:26
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:17:16

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 ☐

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:17:16

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

No ☒

Yes ☐

PC Time stamp	13 AUG 2020 12:09
PC Open Date & Time	13 AUG 2020 11:55
PC Close Date & Time	13 AUG 2020 14:25

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:17:16

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 ☐

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:17:16

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

No ☒

Yes ☐

PC Time stamp	13 AUG 2020 20:54
PC Open Date & Time	13 AUG 2020 15:20
PC Close Date & Time	14 AUG 2020 11:59

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:17:16

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 ☒

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:17:16

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 21:15
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:17:16

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 ☒

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EAB) (1725)

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US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:17:16

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 20:28
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:17:16

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 20:12
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:17:16

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 20:37
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:17:16

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 ☒

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:17:16

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 21:01
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:17:16

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 ☒

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EAB) (1725)

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US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:17:16

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 22:26
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3362125

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 14:04:32

Generated On: 09 Jun 2021 17:17:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362125

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:04:32

Generated On: 09 Jun 2021 17:17:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362125

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 14:04:30

Generated On: 09 Jun 2021 17:17:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362125

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:04:30

Generated On: 09 Jun 2021 17:17:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362125

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 14:04:30

Generated On: 09 Jun 2021 17:17:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362125

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:04:30

Generated On: 09 Jun 2021 17:17:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362125

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 14:04:33

Generated On: 09 Jun 2021 17:17:16

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 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	VISIT2

US3362125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 20 Feb 2021 14:04:33

Generated On: 09 Jun 2021 17:17:16

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)	15 SEP 2020
Time of assessment (00:00-23:59)	13:10 (24 HR)
Vital Signs Date and Time (derived)	15 SEP 2020 13:10
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)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3362125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Feb 2021 14:04:33

Generated On: 09 Jun 2021 17:17:16

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	15 SEP 2020
Time of assessment (00:00-23:59)	14:33 (24 HR)
Vital Signs Date and Time (derived)	15 SEP 2020 14:33
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3362125

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 14:04:33

Generated On: 09 Jun 2021 17:17:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 SEP 2020

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

US3362125

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 20 Feb 2021 14:04:33

Generated On: 09 Jun 2021 17:17:16

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) 15 SEP 2020

What was the treatment time? (00:00-23:59) 14:01 (24 HR)

Treatment Date and Time (derived) 15 SEP 2020 14:01

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

What was the frequency of the study treatment dosing? ONCE

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

US3362125

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 14:04:33

Generated On: 09 Jun 2021 17:17:16

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

15 SEP 2020

Collection time (00:00-23:59)

13:33 (24 HR)

Collection date and time (derived)

15 SEP 2020 13:33

US3362125

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 14:04:33

Generated On: 09 Jun 2021 17:17:16

Collection date (dd MMM yyyy)			15 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:32	15 SEP 2020 13:32
Nasopharyngeal Swab 2	No		

US3362125

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:04:33

Generated On: 09 Jun 2021 17:17:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 14:35

PC Open Date & Time

15 SEP 2020 14:21

PC Close Date & Time

15 SEP 2020 16:51

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:17:16

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 98.6 °F

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

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

PC Time Stamp	15 SEP 2020 20:28
PC Open Date & Time	15 SEP 2020 17:46
PC Close Date & Time	16 SEP 2020 11:59

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:17:16

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

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 22:47

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 23:37

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:17:16

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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 SEP 2020 20:40

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:17:16

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 20:29

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 SEP 2020 22:38

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 SEP 2020 21:50

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 14:36

PC Open Date & Time

15 SEP 2020 14:21

PC Close Date & Time

15 SEP 2020 16:51

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:17:16

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

15 SEP 2020 20:28

PC Open Date & Time

15 SEP 2020 17:46

PC Close Date & Time

16 SEP 2020 11:59

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:17:16

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

16 SEP 2020 22:47

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:17:16

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

17 SEP 2020 23:37

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:17:16

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

18 SEP 2020 20:40

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:17:16

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

19 SEP 2020 20:28

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:17:16

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

20 SEP 2020 22:39

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:17:16

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

21 SEP 2020 21:50

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:17:16

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 ☐

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:17:16

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

No ☒

Yes ☐

PC Time stamp	15 SEP 2020 14:36
PC Open Date & Time	15 SEP 2020 14:21
PC Close Date & Time	15 SEP 2020 16:51

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:17:16

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 ☐

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:17:16

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

No ☒

Yes ☐

PC Time stamp	15 SEP 2020 20:29
PC Open Date & Time	15 SEP 2020 17:46
PC Close Date & Time	16 SEP 2020 11:59

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

93 of 2664

EAB) (1725)

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:17:16

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 22:47
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

95 of 2664

EAB) (1725)

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:17:16

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 23:38
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

97 of 2664

EAB) (1725)

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:17:16

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 20:40
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:17:16

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 ☒

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:17:16

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 20:29
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:17:16

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 ☒

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:17:16

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 22:39
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:17:16

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 ☒

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:17:16

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 21:51
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3362125

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 14:04:30

Generated On: 09 Jun 2021 17:17:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362125

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:04:30

Generated On: 09 Jun 2021 17:17:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362125

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 14:04:30

Generated On: 09 Jun 2021 17:17:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362125

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:04:30

Generated On: 09 Jun 2021 17:17:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362125

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 14:04:32

Generated On: 09 Jun 2021 17:17:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362125

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:04:31

Generated On: 09 Jun 2021 17:17:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362125

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 14:04:33

Generated On: 09 Jun 2021 17:17:16

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 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

US3362125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 20 Feb 2021 14:04:33

Generated On: 09 Jun 2021 17:17:16

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	13 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	12:55 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 12:55
Temperature (<i>xxx.x</i>)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	73 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3362125

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 14:04:33

Generated On: 09 Jun 2021 17:17:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 OCT 2020

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

US3362125

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 14:04:33

Generated On: 09 Jun 2021 17:17:16

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

13 OCT 2020

Collection time (00:00-23:59)

13:05 (24 HR)

Collection date and time (derived)

13 OCT 2020 13:05

US3362125

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:04:33

Generated On: 09 Jun 2021 17:17:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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 22:45:38
Patient Cloud Open Date & Time	13 OCT 2020 00:01
Patient Cloud Close Date & Time	17 OCT 2020 23:59

US3362125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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 ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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

20 OCT 2020 07:51:53

Patient Cloud Open Date & Time

20 OCT 2020 00:01

Patient Cloud Close Date & Time

24 OCT 2020 23:59

US3362125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 OCT 2020 07:04:11
Patient Cloud Open Date & Time	27 OCT 2020 00:01
Patient Cloud Close Date & Time	31 OCT 2020 23:59

US3362125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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 <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	True
Chills	True
Cough	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	True
Body aches	True
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	True
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	10 NOV 2020 09:28:34
Patient Cloud Open Date & Time	10 NOV 2020 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	
119 of 2664	

US3362125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

14 NOV 2020 23:59

US3362125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 NOV 2020 07:45:48
Patient Cloud Open Date & Time	17 NOV 2020 00:01
Patient Cloud Close Date & Time	21 NOV 2020 23:59

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 NOV 2020 07:47:36

Patient Cloud Open Date & Time

21 NOV 2020 00:01

Patient Cloud Close Date & Time

25 NOV 2020 23:59

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 NOV 2020 07:44:30
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 DEC 2020 16:06:22

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 DEC 2020 15:47:45
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

19 DEC 2020 08:52:56

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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 07:50:57

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 JAN 2021 20:45:37

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 JAN 2021 08:13:40

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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	16 JAN 2021 22:16:21
Patient Cloud Open Date & Time	16 JAN 2021 00:01
Patient Cloud Close Date & Time	20 JAN 2021 23:59

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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	23 JAN 2021 02:30:25
Patient Cloud Open Date & Time	23 JAN 2021 00:01
Patient Cloud Close Date & Time	27 JAN 2021 23:59

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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 07:31:14

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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	06 FEB 2021 06:55:43
Patient Cloud Open Date & Time	06 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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 08:58:25
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 FEB 2021 08:26:46

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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	27 FEB 2021 13:58:34
Patient Cloud Open Date & Time	27 FEB 2021 00:01
Patient Cloud Close Date & Time	03 MAR 2021 23:59

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

06 MAR 2021 06:44:11

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

13 MAR 2021 08:33:20

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	22 MAR 2021 07:19:12
Patient Cloud Open Date & Time	20 MAR 2021 00:01
Patient Cloud Close Date & Time	24 MAR 2021 23:59

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 MAR 2021 08:38:34

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 APR 2021 08:02:47
Patient Cloud Open Date & Time	03 APR 2021 00:01
Patient Cloud Close Date & Time	07 APR 2021 23:59

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

10 APR 2021 09:19:06

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

17 APR 2021 08:35:43

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 APR 2021 12:20:47

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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 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	01 MAY 2021 07:09:03
Patient Cloud Open Date & Time	01 MAY 2021 00:01
Patient Cloud Close Date & Time	05 MAY 2021 23:59

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

DAY 278

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

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

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

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

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

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

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 ☐

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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="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"/>

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

DAY 292

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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"/>

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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"/>

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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 ☐

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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="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"/>

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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="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"/>

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

DAY 348

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

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

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

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

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

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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 ☐

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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 ☐

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

DAY 390

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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 ☐

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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"/>

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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
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Patient Cloud Close Date & Time	29 SEP 2021 23:59
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US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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"/>

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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 ☐

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

DAY 439

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

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

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

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

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

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

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 ☐

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

Patient Cloud Open Date & Time	23 OCT 2021 00:01
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Patient Cloud Close Date & Time	27 OCT 2021 23:59
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US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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"/>

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

DAY 453

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

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

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

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

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

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

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 ☐

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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="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"/>

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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°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 ☐

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	04 DEC 2021 00:01
Patient Cloud Close Date & Time	08 DEC 2021 23:59

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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="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"/>

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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 ☐

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

DAY 523

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

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

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

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

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

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

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

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 JAN 2022 00:01
Patient Cloud Close Date & Time	26 JAN 2022 23:59

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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 ☐

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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"/>

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 FEB 2022 00:01
Patient Cloud Close Date & Time	09 FEB 2022 23:59

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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 ☐

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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 ☐

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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 ☐

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

DAY 586

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

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

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

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

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

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

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

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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 ☐

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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"/>

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

Patient Cloud Open Date & Time	02 APR 2022 00:01
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Patient Cloud Close Date & Time	06 APR 2022 23:59
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US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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"/>

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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"/>

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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"/>

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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"/>

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

DAY 642

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

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

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

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

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

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

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

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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"/>

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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 ☐

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUN 2022 00:01
Patient Cloud Close Date & Time	08 JUN 2022 23:59

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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"/>

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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 ☐

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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"/>

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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 ☐

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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"/>

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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"/>

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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"/>

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	13 AUG 2022 00:01
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Patient Cloud Close Date & Time	17 AUG 2022 23:59
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US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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="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"/>

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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 ☐

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

[Patient Cloud Open Date & Time](#)

10 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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 ☐

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

DAY 789

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

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

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

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

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

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

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

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

US3362125

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:17:16

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		27 FEB 2021 13:58:51

US3362125

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 06 Mar 2021 04:20:52

Generated On: 09 Jun 2021 17:17:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362125

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 06 Mar 2021 04:20:52

Generated On: 09 Jun 2021 17:17:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362125

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 00:17:26

Generated On: 09 Jun 2021 17:17:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362125

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 00:17:26

Generated On: 09 Jun 2021 17:17:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362125

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 00:17:26

Generated On: 09 Jun 2021 17:17:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362125

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 00:17:26

Generated On: 09 Jun 2021 17:17:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362125

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 00:17:26

Generated On: 09 Jun 2021 17:17:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362125

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 00:17:26

Generated On: 09 Jun 2021 17:17:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362125

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 24 Apr 2021 00:17:26

Generated On: 09 Jun 2021 17:17:16

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3362125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 24 Apr 2021 00:17:26

Generated On: 09 Jun 2021 17:17:16

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 MAR 2021
Time of assessment (00:00-23:59)	09:55 (24 HR)
Vital Signs Date and Time (derived)	22 MAR 2021 09:55
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)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	93 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3362125

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Apr 2021 00:17:26

Generated On: 09 Jun 2021 17:17:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 MAR 2021

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

US3362125

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Apr 2021 00:17:26

Generated On: 09 Jun 2021 17:17:16

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 MAR 2021

Collection time (00:00-23:59)

10:08 (24 HR)

Collection date and time (derived)

22 MAR 2021 10:08

US3362125

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 00:17:26

Generated On: 09 Jun 2021 17:17:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362125

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 00:17:26

Generated On: 09 Jun 2021 17:17:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362125

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 00:17:26

Generated On: 09 Jun 2021 17:17:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362125

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:16

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

US3362125

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:16

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

Date of Contact	9 NOV 2020
Time of Contact	11:05
Date and Time of Contact (derived)	9 NOV 2020 11:05
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input checked="" type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

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"/>

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

	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	9 NOV 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	37.0 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"/>

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

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

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

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

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

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"/>

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

	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	8 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	100.9 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

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

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

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

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

Symptom Day

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

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	10 NOV 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

	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"/>

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

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

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

Symptom Day

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

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

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

Date	11 NOV 2020
------	-------------

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

O2 Saturation	94 %
---------------	------

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

Temperature	96.8 F
-------------	--------

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

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

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

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

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

	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"/>

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

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

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

Symptom Day

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

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Form: Symptom Log (5)

Data signed: (b) (4) 24 Apr 2021 00:17:25

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	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	12 NOV 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	96.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

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

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Form: Symptom Log (5)

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

Symptom Day

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

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

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

Date	13 NOV 2020
------	-------------

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

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

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

Temperature	96.5 F
-------------	--------

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

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

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

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

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Form: Symptom Log (6)

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

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

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

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

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

Symptom Day

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

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Form: Symptom Log (7)

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	14 NOV 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	98 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (7)

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

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

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Form: Symptom Log (7)

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

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

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Form: Symptom Log (8)

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

Symptom Day

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

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Form: Symptom Log (8)

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	15 NOV 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
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"/>

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Form: Symptom Log (8)

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

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

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

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

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

Symptom Day

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

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	16 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
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"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

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

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

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

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

Symptom Day

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

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	17 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	96.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

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

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

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

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

Symptom Day

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

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	18 NOV 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	96.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (11)

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

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

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Form: Symptom Log (11)

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

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

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

Symptom Day

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

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Form: Symptom Log (12)

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	19 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (12)

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

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

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Form: Symptom Log (12)

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Form: Symptom Log (13)

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

Symptom Day

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

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Form: Symptom Log (13)

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	20 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	96.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (13)

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

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

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

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

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Form: Symptom Log (14)

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

Symptom Day

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

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	21 NOV 2020	
Assessment Not Done	False	
O2 Saturation	94 %	
O2 Saturation Units	%	
Temperature	96.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

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

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

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

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

Symptom Day

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

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	22 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

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

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

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

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Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

Date of Visit	9 NOV 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of Test	9 NOV 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	1

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

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

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

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

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

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

If Yes, provide:

Start Date _____

End Date _____

Oxygen Saturation _____

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

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

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

Start Date _____

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 24 Apr 2021 00:17:25

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

Ventilator Support:

High-Flow Oxygen?

Yes ☐

No ☒

Start Date

End Date

Non-Invasive Ventilation?

Yes ☐

No ☒

Start Date

End Date

Mechanical Ventilation?

Yes ☐

No ☒

Start Date

End Date

ECMO?

Yes ☐

No ☒

Start Date

End Date

Evidence of Shock:

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

Yes ☐

No ☒

Start Date

End Date

Evidence of Shock Requires Vasopressors

Yes ☐

No ☒

Start Date

End Date

Acute Renal Dysfunction?

Yes ☐

No ☒

Start Date

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 24 Apr 2021 00:17:25

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Hepatic Dysfunction? Yes ☐
No ☒

Start Date

Neurologic Dysfunction? Yes ☐
No ☒

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☐
No ☒

Date of Assessment

Radiographical Evidence Yes ☐
No ☒

Date of Assessment

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

Start Date

End Date

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

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Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	11 NOV 2020
Day 5	Yes	13 NOV 2020
Day 7	Yes	15 NOV 2020
Day 9	Yes	17 NOV 2020
Day 14	Yes	24 NOV 2020
Day 21	Yes	30 NOV 2020
Day 28	Yes	07 DEC 2020

US3362125

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3362125

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	9 NOV 2020
Time of assessment (<i>00:00-23:59</i>)	11:05 (24 HR)
Vital Signs Date and Time (derived)	9 NOV 2020 11:05
Height (<i>xxx.x</i>)	183 cm
Weight (<i>xxx.x</i>)	96.9 kg
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>)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	145 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	92 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3362125

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

9 NOV 2020

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

US3362125

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 00:17:25

Generated On: 09 Jun 2021 17:17:16

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

9 NOV 2020

US3362125

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	7 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3362125

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	7 DEC 2020
Time of assessment (00:00-23:59)	09:35 (24 HR)
Vital Signs Date and Time (derived)	7 DEC 2020 09:35
Height (xxx.x)	183 cm
Weight (xxx.x)	96.9 kg
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3362125

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

7 DEC 2020

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

US3362125

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 00:17:25

Generated On: 09 Jun 2021 17:17:16

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

7 DEC 2020

US3362125

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

Form: Visit Date

Data signed: (b) (4) 24 Apr 2021 00:17:26

Generated On: 09 Jun 2021 17:17:16

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

Visit date (dd MMM yyyy)	22 FEB 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3362125

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

Form: Unblinding

Data signed: (b) (4) 24 Apr 2021 00:17:26

Generated On: 09 Jun 2021 17:17:16

Date of updated informed consent (<i>dd MMM yyyy</i>)	22 FEB 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	22 FEB 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3362125

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 24 Apr 2021 00:17:26

Generated On: 09 Jun 2021 17:17:16

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

US3362125

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 24 Apr 2021 00:17:26

Generated On: 09 Jun 2021 17:17:16

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)	22 FEB 2021
Time of assessment (00:00-23:59)	09:59 (24 HR)
Vital Signs Date and Time (derived)	22 FEB 2021 09:59
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)	52 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	160 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	93 mmHg
Diastolic Blood Pressure units	MMHG

US3362125

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 24 Apr 2021 00:17:26

Generated On: 09 Jun 2021 17:17:16

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)	22 FEB 2021
Time of assessment (00:00-23:59)	11:02 (24 HR)
Vital Signs Date and Time (derived)	22 FEB 2021 11:02
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	161 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3362125

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

Form: Physical Examination

Data signed: (b) (4) 24 Apr 2021 00:17:26

Generated On: 09 Jun 2021 17:17:16

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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

Form: Exposure

Data signed: (b) (4) 24 Apr 2021 00:17:26

Generated On: 09 Jun 2021 17:17:16

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) 22 FEB 2021

What was the treatment time? (00:00-23:59) 10:22 (24 HR)

Treatment Date and Time (derived) 22 FEB 2021 10:22

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

What was the frequency of the study treatment dosing? ONCE

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

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Apr 2021 00:17:26

Generated On: 09 Jun 2021 17:17:16

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 FEB 2021

Collection time (00:00-23:59)

09:47 (24 HR)

Collection date and time (derived)

22 FEB 2021 09:47

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 24 Apr 2021 00:17:26

Generated On: 09 Jun 2021 17:17:16

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 FEB 2021
Collection time (00:00 - 23:59)	09:50
Collection Date and Time (derived)	22 FEB 2021 09:50

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

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 00:17:26

Generated On: 09 Jun 2021 17:17:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 00:17:26

Generated On: 09 Jun 2021 17:17:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362125

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 00:17:26

Generated On: 09 Jun 2021 17:17:16

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

US3362125

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

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

Visit date (dd MMM yyyy)	22 MAR 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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US3362125

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

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)	22 MAR 2021
Time of assessment (00:00-23:59)	09:55 (24 HR)
Vital Signs Date and Time (derived)	22 MAR 2021 09:55
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)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	93 mmHg
Diastolic Blood Pressure units	MMHG

US3362125

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

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)	22 MAR 2021
Time of assessment (00:00-23:59)	11:05 (24 HR)
Vital Signs Date and Time (derived)	22 MAR 2021 11:05
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)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	143 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3362125

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 MAR 2021

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

US3362125

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

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) 22 MAR 2021

What was the treatment time? (00:00-23:59) 10:33 (24 HR)

Treatment Date and Time (derived) 22 MAR 2021 10:33

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

US3362125

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 00:17:25

Generated On: 09 Jun 2021 17:17:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362125

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 00:17:26

Generated On: 09 Jun 2021 17:17:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362125

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 00:17:26

Generated On: 09 Jun 2021 17:17:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362125

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 24 Apr 2021 00:17:26

Generated On: 09 Jun 2021 17:17:16

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3362125

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 24 Apr 2021 00:17:26

Generated On: 09 Jun 2021 17:17:16

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3362125

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Apr 2021 00:17:26

Generated On: 09 Jun 2021 17:17:16

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.

US3362125

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Apr 2021 00:17:26

Generated On: 09 Jun 2021 17:17:16

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

19 APR 2021

Collection time (00:00-23:59)

09:04 (24 HR)

Collection date and time (derived)

19 APR 2021 09:04

US3362125

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 13 Mar 2021 22:14:00

Generated On: 09 Jun 2021 17:17:16

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3362125

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 14 Apr 2021 23:24:38

Generated On: 09 Jun 2021 17:17:16

AEID	USA-US112-2020-MRNA-1273-P30 1000010
Adverse event	COVID-19
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	8 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	13 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 14 Apr 2021 23:24:38

Generated On: 09 Jun 2021 17:17:16

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

US3362125

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 14 Apr 2021 23:24:38

Generated On: 09 Jun 2021 17:17:16

AEID	USA-US112-2021-MRNA-1273-P30 1000015
Adverse event	COMPLETE AV BLOCK
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	17 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	19 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	17 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	20 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 14 Apr 2021 23:24:38

Generated On: 09 Jun 2021 17:17:16

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 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	False
Concomitant Medication	True
Concomitant Procedure	True
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	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 14 Apr 2021 23:24:38

Generated On: 09 Jun 2021 17:17:16

SUBJECTED CONTACTED BY
SUB-I TO REVIEW HISTORY OF
ELEVATED BLOOD PRESSURE,
NOTIFIED SUB-I IN HOSPITAL-
HAD ROUTINE CARDIOLOGY
APPOINTMENT AND NOTED TO
HAVE COMPLETE HEART
BLOCK, ADMITTED FOR DUAL
CHAMBER PACEMAKER
PLACEMENT, WILL NOTIFY
STAFF WHEN DISCHARGED
AND WILL SIGN MEDICAL
RECORDS RELEASE.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 09 Apr 2021 00:51:40

Generated On: 09 Jun 2021 17:17:16

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

Yes ☒

No ☐

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

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 10 Apr 2021 00:42:29

Generated On: 09 Jun 2021 17:17:16

Name of Medication MINOCYCLINE

Prophylaxis Yes ☐
No ☒

Indication DERMATITIS

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 10 Apr 2021 00:42:29

Generated On: 09 Jun 2021 17:17:16

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 10 Apr 2021 00:42:29

Generated On: 09 Jun 2021 17:17:16

Name of Medication LOSARTAN/HYDROCHLOROTHIAZIDE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 100/25

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 10 Apr 2021 00:42:29

Generated On: 09 Jun 2021 17:17:16

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2010
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 10 Apr 2021 00:42:29

Generated On: 09 Jun 2021 17:17:16

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS

Dose per administration .5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 10 Apr 2021 00:42:29

Generated On: 09 Jun 2021 17:17:16

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		05 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		05 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 10 Apr 2021 00:42:29

Generated On: 09 Jun 2021 17:17:16

Name of Medication FLONASE

Prophylaxis Yes ☐
No ☒

Indication SARS COV-2 POSITIVE

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 10 Apr 2021 00:42:29

Generated On: 09 Jun 2021 17:17:16

	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)	8 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy) 8 NOV 2020		
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="checkbox"/>	

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 10 Apr 2021 00:42:29

Generated On: 09 Jun 2021 17:17:16

Name of Medication BENADRYL

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 12.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 10 Apr 2021 00:42:29

Generated On: 09 Jun 2021 17:17:16

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 10 Apr 2021 00:42:29

Generated On: 09 Jun 2021 17:17:16

Name of Medication CEPHALEXIN

Prophylaxis Yes ☒
No ☐

Indication COMPLETE AV HEART
BLOCK/PACEMAKER
PLACEMENT

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 10 Apr 2021 00:42:29

Generated On: 09 Jun 2021 17:17:16

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	20 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	27 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 10 Apr 2021 00:42:29

Generated On: 09 Jun 2021 17:17:16

Name of Medication NORCO
HYDROCODONE/ACETAMINOP
HEN

Prophylaxis Yes ☐
No ☒

Indication POST-OP PACEMAKER
PLACEMENT

Dose per administration 5/325

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 10 Apr 2021 00:42:29

Generated On: 09 Jun 2021 17:17:16

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	20 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3362125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Apr 2021 00:51:40

Generated On: 09 Jun 2021 17:17:16

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3362125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 09 Apr 2021 00:51:40

Generated On: 09 Jun 2021 17:17:16

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
18 MAR 2021	DUAL CHAMBER PACEMAKER PLACEMENT	Adverse Event	

US3362125

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:17:16

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3362125

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:17:16

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

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

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3362125

Folder: SAE USA-US112-2020-MRNA-1273-P301000010

Form: Safety Report Form

Data signed: (b) (4) 24 Apr 2021 00:17:26

Generated On: 09 Jun 2021 17:17:16

SAEID	USA-US112-2020-MRNA-1273-P301000010
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	2

US3362125

Folder: SAE USA-US112-2020-MRNA-1273-P301000010

Form: Safety Report Form (1)

Data signed: (b) (4) 24 Apr 2021 00:17:26

Generated On: 09 Jun 2021 17:17:16

SAEID	USA-US112-2020-MRNA-1273-P301000010
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	2
Date of submission (Pre-filled from custom function)	16/NOV/2020 11:55
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

US3362125

Folder: SAE USA-US112-2020-MRNA-1273-P301000010

Form: Safety Report Form (2)

Data signed: (b) (4) 24 Apr 2021 00:17:26

Generated On: 09 Jun 2021 17:17:16

SAEID	USA-US112-2020-MRNA-1273-P301000010
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	2
Date of submission (Pre-filled from custom function)	30/NOV/2020 18:28
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

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form

Data signed: (b) (4) 24 Apr 2021 00:17:26

Generated On: 09 Jun 2021 17:17:16

SAEID	USA-US112-2021-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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)	3

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form (1)

Data signed: (b) (4) 24 Apr 2021 00:17:26

Generated On: 09 Jun 2021 17:17:16

SAEID	USA-US112-2021-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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)	3
Date of submission (Pre-filled from custom function)	19/MAR/2021 14:20
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

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form (2)

Data signed: (b) (4) 24 Apr 2021 00:17:26

Generated On: 09 Jun 2021 17:17:16

SAEID	USA-US112-2021-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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)	3
Date of submission (Pre-filled from custom function)	29/MAR/2021 09:50
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

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form (3)

Data signed: (b) (4) 24 Apr 2021 00:17:26

Generated On: 09 Jun 2021 17:17:16

SAEID	USA-US112-2021-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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)	3
Date of submission (Pre-filled from custom function)	12/APR/2021 10:41
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

US3362125 (Prod: Meridian Clinical Research-(Baton Rouge, Louisiana) - Platinum - PPDS)

US3362125

Form: Participant Creation

Generated On: 09 Jun 2021 17:17:16

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered 'US3362125'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 15:34:31

US3362125

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:17:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	13 Aug 2020 16:36:30
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Aug 2020 16:36:30
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 16:36:30
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 16:36:04
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 16:36:04

US3362125

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered '13 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 15:34:32

US3362125

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:17:16

[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 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	13 Aug 2020 16:36:04

US3362125

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:17:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User entered 'SCRN'	System	13 Aug 2020 16:36:30
User entered empty.	System	13 Aug 2020 16:36:04

US3362125

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:17:16

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered (b) (6) 1953'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 15:34:33

US3362125

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:17:16

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered '66'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:29:02

US3362125

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:17:16

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User entered 'YEARS'	System	13 Aug 2020 21:29:02

US3362125

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:17:16

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User entered '66'	System	13 Aug 2020 16:37:05

US3362125

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:17:16

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered 'Male (M)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:29:02

US3362125

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:17:16

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:29:02

US3362125

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:17:16

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered 'I'	(b) (4), (b) (6)	13 Aug 2020 21:29:02

US3362125

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:17:16

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 21:29:02

US3362125

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:17:16

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 21:29:02

US3362125

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:17:16

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 21:29:02

US3362125

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:17:16

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:29:02

US3362125

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:17:16

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 21:29:02

US3362125

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:17:16

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 21:29:02

US3362125

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:17:16

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 21:29:02

US3362125

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:17:16

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 21:29:02

US3362125

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:17:16

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered '13 Aug 2020'	(b) (4), (b) (6)	13 Aug 2020 16:37:05

US3362125

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User entered 'Aug 2020'	System	13 Aug 2020 16:37:05

US3362125

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User entered '2020'	System	13 Aug 2020 16:37:05

US3362125

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:17:16

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered 'Amendment 2 (2)'	(b) (4), (b) (6)	13 Aug 2020 16:37:05

US3362125

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 16:37:05

US3362125

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:17:16

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 16:37:05

US3362125

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:17:16

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 16:37:05

US3362125

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:17:16

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 16:37:05

US3362125

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:17:16

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 15:34:32

US3362125

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:17:16

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User entered 'I'	System	13 Aug 2020 16:37:15

US3362125

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 16:37:15

US3362125

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:17:16

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:29:08

US3362125

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:17:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Essential hypertension, LLT: Essential hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 21:34:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 21:34:11
Data point term sent to Coder	System	13 Aug 2020 21:33:12
User entered 'essential hypertension'	(b) (4), (b) (6)	13 Aug 2020 21:32:43

US3362125

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered 'un UNK 2008'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:32:43

US3362125

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 21:32:43

US3362125

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:17:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:32:43

US3362125

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:17:16

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:32:43

US3362125

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:17:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 21:32:43

US3362125

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User entered 'Jan 2008'	System	13 Aug 2020 21:32:43

US3362125

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User entered '2008'	System	13 Aug 2020 21:32:43

US3362125

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User entered empty.	System	13 Aug 2020 21:32:43

US3362125

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User entered empty.	System	13 Aug 2020 21:32:43

US3362125

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:17:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 21:34:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 21:34:11
Data point term sent to Coder	System	13 Aug 2020 21:33:13
User entered 'hyperlipidemia'	(b) (4), (b) (6)	13 Aug 2020 21:32:57

US3362125

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered 'un UNK 2008'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:32:57

US3362125

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 21:32:57

US3362125

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:17:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:32:57

US3362125

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:17:16

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:32:57

US3362125

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:17:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 21:32:57

US3362125

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:17:16

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User entered 'Jan 2008'	System	13 Aug 2020 21:32:57

US3362125

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User entered '2008'	System	13 Aug 2020 21:32:57

US3362125

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User entered empty.	System	13 Aug 2020 21:32:57

US3362125

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User entered empty.	System	13 Aug 2020 21:32:57

US3362125

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:17:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User closed query 'Per DM CLR: Please review and update the Condition term to reflect the location (e.g. face, bilateral hands, generalised, etc.) of DERMATITIS. Please reconcile with the CM eCRF so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 20:49:44
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Dermatitis, LLT: Dermatitis - version MedDRA\23.0.	Coder Import (b) (4)	29 Sep 2020 19:15:23
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	29 Sep 2020 19:15:23
Data point term sent to Coder	System	29 Sep 2020 17:36:29
Query 'Per DM CLR: Please review and update the Condition term to reflect the location (e.g. face, bilateral hands, generalised, etc.) of DERMATITIS. Please reconcile with the CM eCRF so there is an appropriate match. ' answered with 'RESOLVED' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 17:36:21
Coding entries removed.	(b) (4), (b) (6)	29 Sep 2020 17:36:12
User entered 'DERMATITIS GENERALIZED' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Sep 2020 17:36:12
User opened query 'Per DM CLR: Please review and update the Condition term to reflect the location (e.g. face, bilateral hands, generalised, etc.) of DERMATITIS. Please reconcile with the CM eCRF so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 11:03:25
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Dermatitis, LLT: Dermatitis - version MedDRA\23.0.	Coder Import (b) (4)	13 Aug 2020 21:34:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	13 Aug 2020 21:34:11
Data point term sent to Coder	System	13 Aug 2020 21:33:13

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Folder: Screening

Form: Medical History (3)

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[Condition](#)

Audit	User	Time (GMT)
User entered 'dermatitis'	(b) (4), (b) (6)	13 Aug 2020 21:33:07

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:33:07

US3362125

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 21:33:07

US3362125

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:17:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:33:07

US3362125

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:17:16

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 21:33:07

US3362125

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:17:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 21:33:07

US3362125

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User entered 'Jan 2018'	System	13 Aug 2020 21:33:07

US3362125

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User entered '2018'	System	13 Aug 2020 21:33:07

US3362125

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User entered empty.	System	13 Aug 2020 21:33:07

US3362125

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User entered empty.	System	13 Aug 2020 21:33:07

US3362125

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:17:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial flutter, LLT: Atrial flutter - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 21:35:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 21:35:12
Data point term sent to Coder	System	13 Aug 2020 21:34:14
User entered 'atrial flutter'	(b) (4), (b) (6)	13 Aug 2020 21:33:25

US3362125

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:33:25

US3362125

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 21:33:25

US3362125

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:17:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:33:25

US3362125

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:17:16

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:33:25

US3362125

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:17:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 21:33:25

US3362125

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User entered 'Jan 2015'	System	13 Aug 2020 21:33:25

US3362125

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User entered '2015'	System	13 Aug 2020 21:33:25

US3362125

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User entered 'Jan 2015'	System	13 Aug 2020 21:33:25

US3362125

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User entered '2015'	System	13 Aug 2020 21:33:25

US3362125

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:17:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User coded data point as SOC: Surgical and medical procedures, HLGT: Cardiac therapeutic procedures, HLT: Cardiac therapeutic procedures NEC, PT: Cardiac ablation, LLT: Cardiac ablation - version MedDRA\23.0.	Coder Import (b) (4)	14 Aug 2020 02:55:08
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	14 Aug 2020 02:55:08
Data point term sent to Coder	System	13 Aug 2020 21:34:16
User entered 'Atrial Flutter Ablation'	(b) (4), (b) (6)	13 Aug 2020 21:33:44

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:33:44

US3362125

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 21:33:44

US3362125

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:17:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:33:44

US3362125

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:17:16

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:33:44

US3362125

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:17:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 21:33:44

US3362125

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User entered 'Jan 2015'	System	13 Aug 2020 21:33:44

US3362125

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User entered '2015'	System	13 Aug 2020 21:33:44

US3362125

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User entered 'Jan 2015'	System	13 Aug 2020 21:33:44

US3362125

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User entered '2015'	System	13 Aug 2020 21:33:44

US3362125

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:17:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	24 Nov 2020 18:59:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Nov 2020 18:59:59
Data point term sent to Coder	System	24 Nov 2020 18:59:24
User entered 'seasonal allergies'	Crystal Rowell (b) (4)	24 Nov 2020 18:58:28

US3362125

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered 'un UNK 2005'	Crystal Rowell (b) (4)	24 Nov 2020 18:58:28

US3362125

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered '0'	Crystal Rowell (b) (4)	24 Nov 2020 18:58:28

US3362125

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:17:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	24 Nov 2020 18:58:28

US3362125

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:17:16

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered empty.	Crystal Rowell (b) (4)	24 Nov 2020 18:58:28

US3362125

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:17:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered '0'	Crystal Rowell (b) (4)	24 Nov 2020 18:58:28

US3362125

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:17:16

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User entered 'Jan 2005'	System	24 Nov 2020 18:58:28

US3362125

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User entered '2005'	System	24 Nov 2020 18:58:28

US3362125

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User entered empty.	System	24 Nov 2020 18:58:28

US3362125

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User entered empty.	System	24 Nov 2020 18:58:28

US3362125

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:32:22

US3362125

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered '13 Aug 2020'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:32:22

US3362125

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
Query 'Per CDM: Please confirm if time 10:40 is AM or PM. Thank you!' canceled (Site from DM).	(b) (4)	25 Sep 2020 10:32:15
User opened query 'Per CDM: Please confirm if time 10:40 is AM or PM. Thank you!' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 09:50:27
User entered '10:40'		13 Aug 2020 21:32:22

US3362125

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User entered '13 Aug 2020 10:40'	System	13 Aug 2020 21:32:22

US3362125

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered '183' cm	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:32:22
DataPoint set to visible.	System	13 Aug 2020 16:37:15

US3362125

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered '96.9' kg	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:32:22
DataPoint set to visible.	System	13 Aug 2020 16:37:15

US3362125

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
Amendment Manager: User entered '28.93487'	System	16 Sep 2020 23:55:18
User entered '28.9'	System	13 Aug 2020 21:32:22
DataPoint set to visible.	System	13 Aug 2020 16:37:15

US3362125

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User entered 'kg/m2'	System	13 Aug 2020 21:32:22
DataPoint set to visible.	System	13 Aug 2020 16:37:15

US3362125

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 20:54:35
User entered '36.7' C	(b) (4), (b) (6)	13 Aug 2020 21:32:22

US3362125

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 20:54:35
User entered 'Oral (Oral)'	(b) (4), (b) (6)	13 Aug 2020 21:32:22

US3362125

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:32:22

US3362125

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	24 Sep 2020 20:54:49
User entered missing code ND - Not Done; reason for change Data Entry Error	System	24 Sep 2020 20:54:49
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4), (b) (6)	24 Sep 2020 20:54:35
User entered '7ND' (non-conformant).	(b) (4), (b) (6)	24 Sep 2020 20:54:35
User entered '74'	(b) (4), (b) (6)	13 Aug 2020 21:32:22

US3362125

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User entered 'bpm'	System	24 Sep 2020 20:54:49
User entered empty.	System	24 Sep 2020 20:54:35
User entered 'bpm'	System	13 Aug 2020 21:32:22

US3362125

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 20:54:35
User entered '18'	(b) (4), (b) (6)	13 Aug 2020 21:32:22

US3362125

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User entered 'breaths/min'	System	13 Aug 2020 21:32:22

US3362125

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 20:54:35
User entered '160'	(b) (4), (b) (6)	13 Aug 2020 21:32:22

US3362125

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User entered 'mmHg'	System	13 Aug 2020 21:32:22

US3362125

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 20:54:35
User entered '90'	(b) (4), (b) (6)	13 Aug 2020 21:32:22

US3362125

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User entered 'mmHg'	System	13 Aug 2020 21:32:22

US3362125

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42

US3362125

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42

US3362125

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:17:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 21:43:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 21:30:58

US3362125

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:17:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	16 Sep 2020 21:43:31
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 21:43:31
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	15 Sep 2020 20:44:52
User entered '13 Aug 2020'	(b) (4), (b) (6)	13 Aug 2020 21:30:58

US3362125

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:17:16

[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 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:30:41

US3362125

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:17:16

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 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:30:41

US3362125

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:17:16

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 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:30:41

US3362125

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:17:16

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 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:30:41

US3362125

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:17:16

[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 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:30:41

US3362125

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:17:16

[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 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:30:41

US3362125

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:17:16

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 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:30:41

US3362125

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:17:16

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 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:30:41

US3362125

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:17:16

[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 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:30:41

US3362125

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:17:16

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 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:30:41

US3362125

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:17:16

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 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:30:41

US3362125

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:17:16

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 21:30:41

US3362125

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:17:16

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered (b) (6) member, frequent gatherings. Babysitting grandkids'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:30:41

US3362125

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:17:16

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 21:30:41

US3362125

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:17:16

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:30:41

US3362125

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:17:16

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 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:30:41

US3362125

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:17:16

[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 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:30:41

US3362125

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:17:16

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 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:30:41

US3362125

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:17:16

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered 'I'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:30:41

US3362125

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:17:16

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 21:30:41

US3362125

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:17:16

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:35:42
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:18:01
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 21:30:41

US3362125

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:17:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 16:37:27

US3362125

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered '13 Aug 2020'	(b) (4), (b) (6)	13 Aug 2020 16:37:27

US3362125

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:17:16

[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 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	13 Aug 2020 16:37:27

US3362125

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:17:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User entered 'VISIT1'	System	13 Aug 2020 16:37:27

US3362125

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered '13 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 16:14:53

US3362125

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:17:16

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 04:10:37
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:10:37
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Aug 2020 16:14:53
User entered '185749' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 16:14:53

US3362125

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:17:16

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 16:14:53

US3362125

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:17:16

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 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:34:29

US3362125

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:17:16

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 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:34:29

US3362125

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:17:16

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:34:29

US3362125

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:17:16

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:34:29

US3362125

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:17:16

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 21:34:29

US3362125

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:17:16

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 20:53:31
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:19:40
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:01:04

US3362125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:17:16

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 20:53:55
User entered '183' cm	(b) (4), (b) (6)	13 Aug 2020 21:36:01

US3362125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:17:16

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 20:53:55
User entered '96.9' kg	(b) (4), (b) (6)	13 Aug 2020 21:36:01

US3362125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:17:16

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 20:53:55
User entered '183' cm	(b) (4), (b) (6)	13 Aug 2020 21:36:01

US3362125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:17:16

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 20:53:55
User entered '96.9' kg	(b) (4), (b) (6)	13 Aug 2020 21:36:01

US3362125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	13 Aug 2020 21:36:01

US3362125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:36:01

US3362125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered '13 Aug 2020'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:36:01

US3362125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered '10:40'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:36:01

US3362125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User entered '13 Aug 2020 10:40'	System	13 Aug 2020 21:36:01

US3362125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered '36.7' C	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:36:01

US3362125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:36:01

US3362125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:36:01

US3362125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered '74'	(b) (4), (b) (6)	13 Aug 2020 21:36:01

US3362125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User entered 'bpm'	System	13 Aug 2020 21:36:01

US3362125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered '18'	(b) (4), (b) (6)	13 Aug 2020 21:36:01

US3362125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User entered 'breaths/min'	System	13 Aug 2020 21:36:01

US3362125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	14 Aug 2020 14:49:17
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS per Investigator' (Site from System).	(b) (4), (b) (6)	13 Aug 2020 21:36:17
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	13 Aug 2020 21:36:01
User entered '163'	(b) (4), (b) (6)	13 Aug 2020 21:36:01

US3362125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User entered 'mmHg'	System	13 Aug 2020 21:36:01

US3362125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered '97'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:36:01

US3362125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User entered 'mmHg'	System	13 Aug 2020 21:36:01

US3362125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:17:16

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 20:53:55
User entered '183' cm	(b) (4), (b) (6)	13 Aug 2020 21:36:01

US3362125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:17:16

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 20:53:55
User entered '96.9' kg	(b) (4), (b) (6)	13 Aug 2020 21:36:01

US3362125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	13 Aug 2020 21:36:01

US3362125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:36:01

US3362125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered '13 Aug 2020'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:36:01

US3362125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
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 10:33:39
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 21:36:32
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 21:36:01
User entered '12:05'	(b) (4), (b) (6)	13 Aug 2020 21:36:01

US3362125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User entered '13 Aug 2020 12:05'	System	13 Aug 2020 21:36:01

US3362125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered '36.5' C	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:36:01

US3362125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:36:01

US3362125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:36:01

US3362125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered '62'	(b) (4), (b) (6)	13 Aug 2020 21:36:01

US3362125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User entered 'bpm'	System	13 Aug 2020 21:36:01

US3362125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered '18'	(b) (4), (b) (6)	13 Aug 2020 21:36:01

US3362125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User entered 'breaths/min'	System	13 Aug 2020 21:36:01

US3362125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered '150'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:36:01

US3362125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User entered 'mmHg'	System	13 Aug 2020 21:36:01

US3362125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered '88'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:36:01

US3362125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User entered 'mmHg'	System	13 Aug 2020 21:36:01

US3362125

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:17:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:36:44

US3362125

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:17:16

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered '13 Aug 2020'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:36:44

US3362125

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:17:16

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 16:38:28

US3362125

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:17:16

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 16:38:28

US3362125

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:17:16

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 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 16:38:28

US3362125

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:17:16

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User entered 'MRNA-1273 OR PLACEBO'	System	13 Aug 2020 16:38:28

US3362125

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:17:16

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered '13 Aug 2020'	(b) (4), (b) (6)	13 Aug 2020 16:38:28

US3362125

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:17:16

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered '11:35'	(b) (4), (b) (6)	13 Aug 2020 16:38:28

US3362125

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:17:16

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User entered '13 Aug 2020 11:35'	System	13 Aug 2020 16:38:28

US3362125

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:17:16

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	13 Aug 2020 16:38:28

US3362125

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:17:16

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User entered 'ONCE'	System	13 Aug 2020 16:38:28

US3362125

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:17:16

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User entered 'INTRAMUSCULAR'	System	13 Aug 2020 16:38:28

US3362125

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:17:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:37:04

US3362125

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:17:16

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered '13 Aug 2020'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:37:04

US3362125

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:17:16

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered '11:07'	(b) (4), (b) (6)	13 Aug 2020 21:37:04

US3362125

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:17:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User entered '13 Aug 2020 11:07'	System	13 Aug 2020 21:37:04

US3362125

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:17:16

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered '13 Aug 2020'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:37:46

US3362125

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:17:16

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	13 Aug 2020 21:37:46

US3362125

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:17:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:37:46

US3362125

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:17:16

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered '10:56'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:37:46

US3362125

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:17:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User entered '13 Aug 2020 10:56'	System	13 Aug 2020 21:37:46

US3362125

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:17:16

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	13 Aug 2020 21:37:46

US3362125

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:17:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:37:46

US3362125

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:17:16

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:37:46

US3362125

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:17:16

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User entered empty.	System	13 Aug 2020 21:37:46

US3362125

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:17:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:37:55

US3362125

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:17:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User entered 'I'	System	13 Aug 2020 21:37:55

US3362125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	13 Aug 2020 16:38:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:17:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-13T12:02:28', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'e406b496-e40b-4e6f-8546-33fc5ceecf7f' User entered 'Yes (Y)'	System	13 Aug 2020 17:06:20
	System	13 Aug 2020 17:06:20

US3362125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:17:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-13T12:05:59', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'e406b496-e40b-4e6f-8546-33fc5ceecf7f' User entered '97.8'	System	13 Aug 2020 17:06:20
	System	13 Aug 2020 17:06:20

US3362125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-13T12:06:07', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'e406b496-e40b-4e6f-8546-33fc5ceecf7f' User entered 'No (N)'	System	13 Aug 2020 17:06:20
	System	13 Aug 2020 17:06:20

US3362125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-13T12:06:16', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'e406b496-e40b-4e6f-8546-33fc5ceecf7f' User entered '13 Aug 2020 12:06'	System	13 Aug 2020 17:06:20
	System	13 Aug 2020 17:06:20

US3362125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '13 Aug 2020 11:55'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '13 Aug 2020 14:25'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	13 Aug 2020 16:38:28
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:17:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-13T20:52:37', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '21a70615-bb91-4898-b840-f00634339290'	System	14 Aug 2020 01:52:59
User entered 'Yes (Y)'	System	14 Aug 2020 01:52:59

US3362125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:17:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-13T20:52:46', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '21a70615-bb91-4898-b840-f00634339290' User entered '97.7'	System	14 Aug 2020 01:52:59
	System	14 Aug 2020 01:52:59

US3362125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-13T20:52:50', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '21a70615-bb91-4898-b840-f00634339290'	System	14 Aug 2020 01:52:59
User entered 'No (N)'	System	14 Aug 2020 01:52:59

US3362125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-13T20:52:57', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '21a70615-bb91-4898-b840-f00634339290'	System	14 Aug 2020 01:52:59
User entered '13 Aug 2020 20:52'	System	14 Aug 2020 01:52:59

US3362125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '13 Aug 2020 15:20'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	13 Aug 2020 16:38:28
User entered 'Day 2'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:17:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-14T21:14:23', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '61f79c94-05f6-4231-a19c-6e53882078b1' User entered 'Yes (Y)'	System	15 Aug 2020 02:14:45
	System	15 Aug 2020 02:14:45

US3362125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:17:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-14T21:14:32', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '61f79c94-05f6-4231-a19c-6e53882078b1' User entered '97.8'	System	15 Aug 2020 02:14:45
	System	15 Aug 2020 02:14:45

US3362125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-14T21:14:37', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '61f79c94-05f6-4231-a19c-6e53882078b1' User entered 'No (N)'	System	15 Aug 2020 02:14:45
	System	15 Aug 2020 02:14:45

US3362125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-14T21:14:43', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '61f79c94-05f6-4231-a19c-6e53882078b1' User entered '14 Aug 2020 21:14'	System	15 Aug 2020 02:14:45
	System	15 Aug 2020 02:14:45

US3362125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	13 Aug 2020 16:38:28
User entered 'Day 3'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:17:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-15T20:27:28', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '4f5e90c5-9900-443b-91ee-ae2092222772'	System	16 Aug 2020 01:27:50
User entered 'Yes (Y)'	System	16 Aug 2020 01:27:50

US3362125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:17:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-15T20:27:36', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '4f5e90c5-9900-443b-91ee-ae2092222772' User entered '97.8'	System	16 Aug 2020 01:27:50
	System	16 Aug 2020 01:27:50

US3362125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-15T20:27:40', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '4f5e90c5-9900-443b-91ee-ae2092222772'	System	16 Aug 2020 01:27:50
User entered 'No (N)'	System	16 Aug 2020 01:27:50

US3362125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-15T20:27:48', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '4f5e90c5-9900-443b-91ee-ae2092222772'	System	16 Aug 2020 01:27:50
User entered '15 Aug 2020 20:27'	System	16 Aug 2020 01:27:50

US3362125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	13 Aug 2020 16:38:28
User entered 'Day 4'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:17:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-16T20:11:08', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'e6e3e962-a2e0-4c42-b6fb-09dd76eb4b11' User entered 'Yes (Y)'	System	17 Aug 2020 01:11:32
	System	17 Aug 2020 01:11:32

US3362125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:17:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-16T20:11:16', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'e6e3e962-a2e0-4c42-b6fb-09dd76eb4b11' User entered '98.3'	System	17 Aug 2020 01:11:32
	System	17 Aug 2020 01:11:32

US3362125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-16T20:11:21', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'e6e3e962-a2e0-4c42-b6fb-09dd76eb4b11'	System	17 Aug 2020 01:11:32
User entered 'No (N)'	System	17 Aug 2020 01:11:32

US3362125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-16T20:11:31', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'e6e3e962-a2e0-4c42-b6fb-09dd76eb4b11' User entered '16 Aug 2020 20:11'	System	17 Aug 2020 01:11:32
	System	17 Aug 2020 01:11:32

US3362125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	13 Aug 2020 16:38:28
User entered 'Day 5'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:17:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-17T20:36:14', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'f2226579-7178-4af2-a4c6-9a5b3a189f15' User entered 'Yes (Y)'	System	18 Aug 2020 01:36:40
	System	18 Aug 2020 01:36:40

US3362125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:17:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-17T20:36:22', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'f2226579-7178-4af2-a4c6-9a5b3a189f15' User entered '97.3'	System	18 Aug 2020 01:36:40
	System	18 Aug 2020 01:36:40

US3362125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-17T20:36:29', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'f2226579-7178-4af2-a4c6-9a5b3a189f15'	System	18 Aug 2020 01:36:40
User entered 'No (N)'	System	18 Aug 2020 01:36:40

US3362125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-17T20:36:35', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'f2226579-7178-4af2-a4c6-9a5b3a189f15'	System	18 Aug 2020 01:36:40
User entered '17 Aug 2020 20:36'	System	18 Aug 2020 01:36:40

US3362125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	13 Aug 2020 16:38:28
User entered 'Day 6'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:17:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-18T21:00:22', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'b9f39fff-a32d-4e2b-b08b-3901eaf654eb' User entered 'Yes (Y)'	System	19 Aug 2020 02:00:41
	System	19 Aug 2020 02:00:41

US3362125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:17:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-18T21:00:30', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'b9f39fff-a32d-4e2b-b08b-3901eaf654eb' User entered '98.2'	System	19 Aug 2020 02:00:41
	System	19 Aug 2020 02:00:41

US3362125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-18T21:00:34', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'b9f39fff-a32d-4e2b-b08b-3901eaf654eb'	System	19 Aug 2020 02:00:41
User entered 'No (N)'	System	19 Aug 2020 02:00:41

US3362125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-18T21:00:39', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'b9f39fff-a32d-4e2b-b08b-3901eaf654eb'	System	19 Aug 2020 02:00:41
User entered '18 Aug 2020 21:00'	System	19 Aug 2020 02:00:41

US3362125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	13 Aug 2020 16:38:28
User entered 'Day 7'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:17:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-19T22:25:57', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '7051fd92-7c84-43bd-8818-43a6ca02082b' User entered 'Yes (Y)'	System	20 Aug 2020 03:26:19
	System	20 Aug 2020 03:26:19

US3362125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:17:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-19T22:26:09', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '7051fd92-7c84-43bd-8818-43a6ca02082b' User entered '97.9'	System	20 Aug 2020 03:26:19
	System	20 Aug 2020 03:26:19

US3362125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-19T22:26:13', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '7051fd92-7c84-43bd-8818-43a6ca02082b' User entered 'No (N)'	System	20 Aug 2020 03:26:19
	System	20 Aug 2020 03:26:19

US3362125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-19T22:26:16', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '7051fd92-7c84-43bd-8818-43a6ca02082b' User entered '19 Aug 2020 22:26'	System	20 Aug 2020 03:26:19
	System	20 Aug 2020 03:26:19

US3362125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	13 Aug 2020 16:38:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:17:16

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 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-13T12:07:02', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'bac756cc-c41d-40f9-85ad-19307c62382d' User entered 'None (1)'	System	13 Aug 2020 17:07:46
	System	13 Aug 2020 17:07:46

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:17:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-13T12:07:14', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'bac756cc-c41d-40f9-85ad-19307c62382d' User entered 'No (N)'	System	13 Aug 2020 17:07:46
	System	13 Aug 2020 17:07:46

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-13T12:07:24', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'bac756cc-c41d-40f9-85ad-19307c62382d' User entered 'No (N)'	System	13 Aug 2020 17:07:46
	System	13 Aug 2020 17:07:46

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:17:16

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 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-13T12:07:35', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'bac756cc-c41d-40f9-85ad-19307c62382d' User entered 'None (1)'	System	13 Aug 2020 17:07:46
	System	13 Aug 2020 17:07:46

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-13T12:07:44', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'bac756cc-c41d-40f9-85ad-19307c62382d' User entered '13 Aug 2020 12:07'	System	13 Aug 2020 17:07:46
	System	13 Aug 2020 17:07:46

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '13 Aug 2020 11:55'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '13 Aug 2020 14:25'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	13 Aug 2020 16:38:28
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:17:16

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 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-13T20:53:11', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '742329ea-7c1c-4217-b6bd-6f286e018ada' User entered 'None (1)'	System	14 Aug 2020 01:53:53
	System	14 Aug 2020 01:53:53

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:17:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-13T20:53:16', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '742329ea-7c1c-4217-b6bd-6f286e018ada' User entered 'No (N)'	System	14 Aug 2020 01:53:53
	System	14 Aug 2020 01:53:53

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-13T20:53:22', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '742329ea-7c1c-4217-b6bd-6f286e018ada' User entered 'No (N)'	System	14 Aug 2020 01:53:53
	System	14 Aug 2020 01:53:53

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:17:16

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 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-13T20:53:44', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '742329ea-7c1c-4217-b6bd-6f286e018ada' User entered 'None (1)'	System	14 Aug 2020 01:53:53
	System	14 Aug 2020 01:53:53

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-13T20:53:51', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '742329ea-7c1c-4217-b6bd-6f286e018ada' User entered '13 Aug 2020 20:53'	System	14 Aug 2020 01:53:53
	System	14 Aug 2020 01:53:53

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '13 Aug 2020 15:20'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	13 Aug 2020 16:38:28
User entered 'Day 2'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:17:16

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 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-14T21:14:49', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '51d984d3-49d7-4e05-a76c-e880972c6a80' User entered 'None (1)'	System	15 Aug 2020 02:15:05
	System	15 Aug 2020 02:15:05

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:17:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-14T21:14:51', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '51d984d3-49d7-4e05-a76c-e880972c6a80' User entered 'No (N)'	System	15 Aug 2020 02:15:05
	System	15 Aug 2020 02:15:05

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-14T21:14:55', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '51d984d3-49d7-4e05-a76c-e880972c6a80' User entered 'No (N)'	System	15 Aug 2020 02:15:05
	System	15 Aug 2020 02:15:05

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:17:16

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 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-14T21:14:59', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '51d984d3-49d7-4e05-a76c-e880972c6a80' User entered 'None (1)'	System	15 Aug 2020 02:15:05
	System	15 Aug 2020 02:15:05

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-14T21:15:03', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '51d984d3-49d7-4e05-a76c-e880972c6a80' User entered '14 Aug 2020 21:15'	System	15 Aug 2020 02:15:05
	System	15 Aug 2020 02:15:05

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	13 Aug 2020 16:38:28
User entered 'Day 3'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:17:16

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 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-15T20:27:54', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'bf7f33b0-2362-4107-8b38-4cabecffe6e0'	System	16 Aug 2020 01:28:16
User entered 'None (1)'	System	16 Aug 2020 01:28:16

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:17:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-15T20:27:58', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'bf7f33b0-2362-4107-8b38-4cabecffe6e0' User entered 'No (N)'	System	16 Aug 2020 01:28:16
	System	16 Aug 2020 01:28:16

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-15T20:28:02', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'bf7f33b0-2362-4107-8b38-4cabecffe6e0' User entered 'No (N)'	System	16 Aug 2020 01:28:16
	System	16 Aug 2020 01:28:16

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:17:16

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 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-15T20:28:08', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'bf7f33b0-2362-4107-8b38-4cabecffe6e0' User entered 'None (1)'	System	16 Aug 2020 01:28:16
	System	16 Aug 2020 01:28:16

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-15T20:28:12', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'bf7f33b0-2362-4107-8b38-4cabecffe6e0' User entered '15 Aug 2020 20:28'	System	16 Aug 2020 01:28:16
	System	16 Aug 2020 01:28:16

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	13 Aug 2020 16:38:28
User entered 'Day 4'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:17:16

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 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-16T20:11:42', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '415bbb32-d97d-4e18-b678-4156034f5e29' User entered 'None (1)'	System	17 Aug 2020 01:12:08
	System	17 Aug 2020 01:12:08

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:17:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-16T20:11:46', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '415bbb32-d97d-4e18-b678-4156034f5e29' User entered 'No (N)'	System	17 Aug 2020 01:12:08
	System	17 Aug 2020 01:12:08

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-16T20:11:51', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '415bbb32-d97d-4e18-b678-4156034f5e29' User entered 'No (N)'	System	17 Aug 2020 01:12:08
	System	17 Aug 2020 01:12:08

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:17:16

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 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-16T20:11:57', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '415bbb32-d97d-4e18-b678-4156034f5e29'	System	17 Aug 2020 01:12:08
User entered 'None (1)'	System	17 Aug 2020 01:12:08

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-16T20:12:04', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '415bbb32-d97d-4e18-b678-4156034f5e29' User entered '16 Aug 2020 20:12'	System	17 Aug 2020 01:12:08
	System	17 Aug 2020 01:12:08

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	13 Aug 2020 16:38:28
User entered 'Day 5'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:17:16

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 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-17T20:36:43', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '20be9201-3c13-4c74-a71e-12a8e9c3f7d8'	System	18 Aug 2020 01:37:02
User entered 'None (1)'	System	18 Aug 2020 01:37:02

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-17T20:36:47', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '20be9201-3c13-4c74-a71e-12a8e9c3f7d8'	System	18 Aug 2020 01:37:02
User entered 'No (N)'	System	18 Aug 2020 01:37:02

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-17T20:36:51', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '20be9201-3c13-4c74-a71e-12a8e9c3f7d8'	System	18 Aug 2020 01:37:02
User entered 'No (N)'	System	18 Aug 2020 01:37:02

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:17:16

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 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-17T20:36:55', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '20be9201-3c13-4c74-a71e-12a8e9c3f7d8'	System	18 Aug 2020 01:37:02
User entered 'None (1)'	System	18 Aug 2020 01:37:02

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-17T20:36:59', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '20be9201-3c13-4c74-a71e-12a8e9c3f7d8' User entered '17 Aug 2020 20:36'	System	18 Aug 2020 01:37:02
	System	18 Aug 2020 01:37:02

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	13 Aug 2020 16:38:28
User entered 'Day 6'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:17:16

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 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-18T21:00:45', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'b813edfa-a4e6-4be8-ba02-be3a1e569d3f' User entered 'None (1)'	System	19 Aug 2020 02:01:01
	System	19 Aug 2020 02:01:01

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:17:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-18T21:00:48', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'b813edfa-a4e6-4be8-ba02-be3a1e569d3f' User entered 'No (N)'	System	19 Aug 2020 02:01:01
	System	19 Aug 2020 02:01:01

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-18T21:00:52', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'b813edfa-a4e6-4be8-ba02-be3a1e569d3f' User entered 'No (N)'	System	19 Aug 2020 02:01:01
	System	19 Aug 2020 02:01:01

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:17:16

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 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-18T21:00:55', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'b813edfa-a4e6-4be8-ba02-be3a1e569d3f' User entered 'None (1)'	System	19 Aug 2020 02:01:01
	System	19 Aug 2020 02:01:01

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-18T21:00:58', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'b813edfa-a4e6-4be8-ba02-be3a1e569d3f' User entered '18 Aug 2020 21:00'	System	19 Aug 2020 02:01:01
	System	19 Aug 2020 02:01:01

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	13 Aug 2020 16:38:28
User entered 'Day 7'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:17:16

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 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-19T22:26:21', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '4f44226b-60d4-42a8-acb7-cb7484467646' User entered 'None (1)'	System	20 Aug 2020 03:26:37
	System	20 Aug 2020 03:26:37

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:17:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-19T22:26:25', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '4f44226b-60d4-42a8-acb7-cb7484467646' User entered 'No (N)'	System	20 Aug 2020 03:26:37
	System	20 Aug 2020 03:26:37

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-19T22:26:28', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '4f44226b-60d4-42a8-acb7-cb7484467646' User entered 'No (N)'	System	20 Aug 2020 03:26:37
	System	20 Aug 2020 03:26:37

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:17:16

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 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-19T22:26:33', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '4f44226b-60d4-42a8-acb7-cb7484467646' User entered 'None (1)'	System	20 Aug 2020 03:26:37
	System	20 Aug 2020 03:26:37

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-19T22:26:36', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '4f44226b-60d4-42a8-acb7-cb7484467646' User entered '19 Aug 2020 22:26'	System	20 Aug 2020 03:26:37
	System	20 Aug 2020 03:26:37

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	13 Aug 2020 16:38:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:17:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-13T12:07:53', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '5e6036c6-1a99-4e9c-af0d-01b925f6c89c' User entered 'None (0)'	System	13 Aug 2020 17:09:13
	System	13 Aug 2020 17:09:13

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:17:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-13T12:08:02', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '5e6036c6-1a99-4e9c-af0d-01b925f6c89c' User entered 'None (0)'	System	13 Aug 2020 17:09:13
	System	13 Aug 2020 17:09:13

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:17:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-13T12:08:05', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '5e6036c6-1a99-4e9c-af0d-01b925f6c89c' User entered 'None (0)'	System	13 Aug 2020 17:09:13
	System	13 Aug 2020 17:09:13

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:17:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-13T12:08:09', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '5e6036c6-1a99-4e9c-af0d-01b925f6c89c' User entered 'None (0)'	System	13 Aug 2020 17:09:13
	System	13 Aug 2020 17:09:13

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:17:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-13T12:08:58', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '5e6036c6-1a99-4e9c-af0d-01b925f6c89c' User entered 'None (0)'	System	13 Aug 2020 17:09:13
	System	13 Aug 2020 17:09:13

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:17:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-13T12:09:01', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '5e6036c6-1a99-4e9c-af0d-01b925f6c89c' User entered 'None (0)'	System	13 Aug 2020 17:09:13
	System	13 Aug 2020 17:09:13

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:17:16

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 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-13T12:09:05', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '5e6036c6-1a99-4e9c-af0d-01b925f6c89c' User entered 'No (N)'	System	13 Aug 2020 17:09:13
	System	13 Aug 2020 17:09:13

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:17:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-13T12:09:11', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '5e6036c6-1a99-4e9c-af0d-01b925f6c89c' User entered '13 Aug 2020 12:09'	System	13 Aug 2020 17:09:13
	System	13 Aug 2020 17:09:13

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '13 Aug 2020 11:55'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '13 Aug 2020 14:25'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	13 Aug 2020 16:38:28
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:17:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-13T20:53:56', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '25d79474-3802-4d5e-af78-dd614db6876d' User entered 'None (0)'	System	14 Aug 2020 01:54:25
	System	14 Aug 2020 01:54:25

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:17:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-13T20:54:01', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '25d79474-3802-4d5e-af78-dd614db6876d' User entered 'None (0)'	System	14 Aug 2020 01:54:25
	System	14 Aug 2020 01:54:25

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:17:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-13T20:54:04', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '25d79474-3802-4d5e-af78-dd614db6876d' User entered 'None (0)'	System	14 Aug 2020 01:54:25
	System	14 Aug 2020 01:54:25

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:17:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-13T20:54:06', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '25d79474-3802-4d5e-af78-dd614db6876d' User entered 'None (0)'	System	14 Aug 2020 01:54:25
	System	14 Aug 2020 01:54:25

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:17:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-13T20:54:09', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '25d79474-3802-4d5e-af78-dd614db6876d' User entered 'None (0)'	System	14 Aug 2020 01:54:25
	System	14 Aug 2020 01:54:25

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:17:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-13T20:54:11', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '25d79474-3802-4d5e-af78-dd614db6876d' User entered 'None (0)'	System	14 Aug 2020 01:54:25
	System	14 Aug 2020 01:54:25

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:17:16

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 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-13T20:54:16', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '25d79474-3802-4d5e-af78-dd614db6876d' User entered 'No (N)'	System	14 Aug 2020 01:54:25
	System	14 Aug 2020 01:54:25

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:17:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-13T20:54:21', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '25d79474-3802-4d5e-af78-dd614db6876d' User entered '13 Aug 2020 20:54'	System	14 Aug 2020 01:54:25
	System	14 Aug 2020 01:54:25

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '13 Aug 2020 15:20'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	13 Aug 2020 16:38:28
User entered 'Day 2'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:17:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-14T21:15:09', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '2af6f5a0-47e8-4c30-b9c0-8cc93d8ed9ae' User entered 'None (0)'	System	15 Aug 2020 02:15:41
	System	15 Aug 2020 02:15:41

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:17:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-14T21:15:12', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '2af6f5a0-47e8-4c30-b9c0-8cc93d8ed9ae' User entered 'None (0)'	System	15 Aug 2020 02:15:41
	System	15 Aug 2020 02:15:41

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:17:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-14T21:15:18', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '2af6f5a0-47e8-4c30-b9c0-8cc93d8ed9ae' User entered 'None (0)'	System	15 Aug 2020 02:15:41
	System	15 Aug 2020 02:15:41

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:17:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-14T21:15:24', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '2af6f5a0-47e8-4c30-b9c0-8cc93d8ed9ae' User entered 'None (0)'	System	15 Aug 2020 02:15:41
	System	15 Aug 2020 02:15:41

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:17:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-14T21:15:27', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '2af6f5a0-47e8-4c30-b9c0-8cc93d8ed9ae' User entered 'None (0)'	System	15 Aug 2020 02:15:41
	System	15 Aug 2020 02:15:41

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:17:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-14T21:15:30', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '2af6f5a0-47e8-4c30-b9c0-8cc93d8ed9ae' User entered 'None (0)'	System	15 Aug 2020 02:15:41
	System	15 Aug 2020 02:15:41

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:17:16

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 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-14T21:15:34', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '2af6f5a0-47e8-4c30-b9c0-8cc93d8ed9ae'	System	15 Aug 2020 02:15:41
User entered 'No (N)'	System	15 Aug 2020 02:15:41

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:17:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-14T21:15:38', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '2af6f5a0-47e8-4c30-b9c0-8cc93d8ed9ae' User entered '14 Aug 2020 21:15'	System	15 Aug 2020 02:15:41
	System	15 Aug 2020 02:15:41

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	13 Aug 2020 16:38:28
User entered 'Day 3'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:17:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-15T20:28:17', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '763538fd-7b04-444b-8304-4e91256d294b' User entered 'None (0)'	System	16 Aug 2020 01:28:50
	System	16 Aug 2020 01:28:50

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:17:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-15T20:28:20', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '763538fd-7b04-444b-8304-4e91256d294b' User entered 'None (0)'	System	16 Aug 2020 01:28:50
	System	16 Aug 2020 01:28:50

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:17:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-15T20:28:23', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '763538fd-7b04-444b-8304-4e91256d294b' User entered 'None (0)'	System	16 Aug 2020 01:28:50
	System	16 Aug 2020 01:28:50

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:17:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-15T20:28:26', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '763538fd-7b04-444b-8304-4e91256d294b' User entered 'None (0)'	System	16 Aug 2020 01:28:50
	System	16 Aug 2020 01:28:50

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:17:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-15T20:28:29', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '763538fd-7b04-444b-8304-4e91256d294b' User entered 'None (0)'	System	16 Aug 2020 01:28:50
	System	16 Aug 2020 01:28:50

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:17:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-15T20:28:35', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '763538fd-7b04-444b-8304-4e91256d294b' User entered 'None (0)'	System	16 Aug 2020 01:28:50
	System	16 Aug 2020 01:28:50

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:17:16

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 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-15T20:28:45', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '763538fd-7b04-444b-8304-4e91256d294b' User entered 'No (N)'	System	16 Aug 2020 01:28:50
	System	16 Aug 2020 01:28:50

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:17:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-15T20:28:49', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '763538fd-7b04-444b-8304-4e91256d294b' User entered '15 Aug 2020 20:28'	System	16 Aug 2020 01:28:50
	System	16 Aug 2020 01:28:50

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	13 Aug 2020 16:38:28
User entered 'Day 4'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:17:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-16T20:12:14', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'c7102fc2-5116-4a85-80c0-362a93e81122' User entered 'None (0)'	System	17 Aug 2020 01:12:58
	System	17 Aug 2020 01:12:58

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:17:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-16T20:12:17', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'c7102fc2-5116-4a85-80c0-362a93e81122'	System	17 Aug 2020 01:12:58
User entered 'None (0)'	System	17 Aug 2020 01:12:58

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:17:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-16T20:12:20', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'c7102fc2-5116-4a85-80c0-362a93e81122' User entered 'None (0)'	System	17 Aug 2020 01:12:58
	System	17 Aug 2020 01:12:58

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:17:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-16T20:12:23', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'c7102fc2-5116-4a85-80c0-362a93e81122' User entered 'None (0)'	System	17 Aug 2020 01:12:58
	System	17 Aug 2020 01:12:58

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:17:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-16T20:12:28', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'c7102fc2-5116-4a85-80c0-362a93e81122' User entered 'None (0)'	System	17 Aug 2020 01:12:58
	System	17 Aug 2020 01:12:58

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:17:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-16T20:12:46', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'c7102fc2-5116-4a85-80c0-362a93e81122' User entered 'None (0)'	System	17 Aug 2020 01:12:58
	System	17 Aug 2020 01:12:58

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:17:16

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 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-16T20:12:52', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'c7102fc2-5116-4a85-80c0-362a93e81122'	System	17 Aug 2020 01:12:58
User entered 'No (N)'	System	17 Aug 2020 01:12:58

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:17:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-16T20:12:56', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'c7102fc2-5116-4a85-80c0-362a93e81122'	System	17 Aug 2020 01:12:58
User entered '16 Aug 2020 20:12'	System	17 Aug 2020 01:12:58

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	13 Aug 2020 16:38:28
User entered 'Day 5'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:17:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-17T20:37:05', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '0ea504ff-460d-4412-9895-6d3307a6e0e7' User entered 'None (0)'	System	18 Aug 2020 01:37:29
	System	18 Aug 2020 01:37:29

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:17:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-17T20:37:07', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '0ea504ff-460d-4412-9895-6d3307a6e0e7' User entered 'None (0)'	System	18 Aug 2020 01:37:29
	System	18 Aug 2020 01:37:29

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:17:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-17T20:37:10', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '0ea504ff-460d-4412-9895-6d3307a6e0e7' User entered 'None (0)'	System	18 Aug 2020 01:37:29
	System	18 Aug 2020 01:37:29

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:17:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-17T20:37:12', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '0ea504ff-460d-4412-9895-6d3307a6e0e7' User entered 'None (0)'	System	18 Aug 2020 01:37:29
	System	18 Aug 2020 01:37:29

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:17:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-17T20:37:14', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '0ea504ff-460d-4412-9895-6d3307a6e0e7' User entered 'None (0)'	System	18 Aug 2020 01:37:29
	System	18 Aug 2020 01:37:29

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:17:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-17T20:37:18', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '0ea504ff-460d-4412-9895-6d3307a6e0e7' User entered 'None (0)'	System	18 Aug 2020 01:37:29
	System	18 Aug 2020 01:37:29

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:17:16

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 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-17T20:37:23', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '0ea504ff-460d-4412-9895-6d3307a6e0e7' User entered 'No (N)'	System	18 Aug 2020 01:37:29
	System	18 Aug 2020 01:37:29

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:17:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-17T20:37:27', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '0ea504ff-460d-4412-9895-6d3307a6e0e7' User entered '17 Aug 2020 20:37'	System	18 Aug 2020 01:37:29
	System	18 Aug 2020 01:37:29

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	13 Aug 2020 16:38:28
User entered 'Day 6'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:17:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-18T21:01:03', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '4833c295-7dbc-4fe2-82a7-6bac839beb7e' User entered 'None (0)'	System	19 Aug 2020 02:01:26
	System	19 Aug 2020 02:01:26

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:17:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-18T21:01:05', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '4833c295-7dbc-4fe2-82a7-6bac839beb7e' User entered 'None (0)'	System	19 Aug 2020 02:01:26
	System	19 Aug 2020 02:01:26

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:17:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-18T21:01:07', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '4833c295-7dbc-4fe2-82a7-6bac839beb7e' User entered 'None (0)'	System	19 Aug 2020 02:01:26
	System	19 Aug 2020 02:01:26

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:17:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-18T21:01:09', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '4833c295-7dbc-4fe2-82a7-6bac839beb7e' User entered 'None (0)'	System	19 Aug 2020 02:01:26
	System	19 Aug 2020 02:01:26

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:17:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-18T21:01:11', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '4833c295-7dbc-4fe2-82a7-6bac839beb7e' User entered 'None (0)'	System	19 Aug 2020 02:01:26
	System	19 Aug 2020 02:01:26

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:17:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-18T21:01:13', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '4833c295-7dbc-4fe2-82a7-6bac839beb7e' User entered 'None (0)'	System	19 Aug 2020 02:01:26
	System	19 Aug 2020 02:01:26

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:17:16

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 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-18T21:01:20', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '4833c295-7dbc-4fe2-82a7-6bac839beb7e' User entered 'No (N)'	System	19 Aug 2020 02:01:26
	System	19 Aug 2020 02:01:26

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:17:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-18T21:01:23', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '4833c295-7dbc-4fe2-82a7-6bac839beb7e' User entered '18 Aug 2020 21:01'	System	19 Aug 2020 02:01:26
	System	19 Aug 2020 02:01:26

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	13 Aug 2020 16:38:28
User entered 'Day 7'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:17:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-19T22:26:41', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '1af1fc9a-fab7-44d2-aa56-4a640931b61c' User entered 'None (0)'	System	20 Aug 2020 03:27:01
	System	20 Aug 2020 03:27:01

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:17:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-19T22:26:43', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '1af1fc9a-fab7-44d2-aa56-4a640931b61c' User entered 'None (0)'	System	20 Aug 2020 03:27:01
	System	20 Aug 2020 03:27:01

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:17:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-19T22:26:45', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '1af1fc9a-fab7-44d2-aa56-4a640931b61c' User entered 'None (0)'	System	20 Aug 2020 03:27:01
	System	20 Aug 2020 03:27:01

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:17:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-19T22:26:48', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '1af1fc9a-fab7-44d2-aa56-4a640931b61c' User entered 'None (0)'	System	20 Aug 2020 03:27:01
	System	20 Aug 2020 03:27:01

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:17:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-19T22:26:50', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '1af1fc9a-fab7-44d2-aa56-4a640931b61c' User entered 'None (0)'	System	20 Aug 2020 03:27:01
	System	20 Aug 2020 03:27:01

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:17:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-19T22:26:52', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '1af1fc9a-fab7-44d2-aa56-4a640931b61c' User entered 'None (0)'	System	20 Aug 2020 03:27:01
	System	20 Aug 2020 03:27:01

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:17:16

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 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-19T22:26:56', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '1af1fc9a-fab7-44d2-aa56-4a640931b61c' User entered 'No (N)'	System	20 Aug 2020 03:27:01
	System	20 Aug 2020 03:27:01

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:17:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-08-19T22:26:59', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '1af1fc9a-fab7-44d2-aa56-4a640931b61c' User entered '19 Aug 2020 22:26'	System	20 Aug 2020 03:27:01
	System	20 Aug 2020 03:27:01

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 16:38:28

US3362125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 16:38:28

US3362125

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 17:39:52

US3362125

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered '21 Aug 2020'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:39:52

US3362125

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:39:52

US3362125

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:39:52

US3362125

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 17:40:01

US3362125

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User entered 'I'	System	21 Aug 2020 17:40:01

US3362125

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 14:54:33

US3362125

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:31
User entered '28 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 14:54:33

US3362125

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:31
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 14:54:33

US3362125

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:31
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Aug 2020 14:54:33

US3362125

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 14:54:52

US3362125

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:26
User entered 'I'	System	28 Aug 2020 14:54:52

US3362125

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 14:19:26

US3362125

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:31
User entered '3 Sep 2020'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:19:26

US3362125

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:31
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:19:26

US3362125

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:31
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 14:19:26

US3362125

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:19:30

US3362125

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User entered 'I'	System	03 Sep 2020 14:19:30

US3362125

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:17:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:44:52

US3362125

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered '15 Sep 2020'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:44:52

US3362125

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:17:16

[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 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:44:52

US3362125

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:17:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User entered 'VISIT2'	System	15 Sep 2020 20:44:52

US3362125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	15 Sep 2020 20:46:56

US3362125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:46:56

US3362125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered '15 Sep 2020'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:46:56

US3362125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered '13:10'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:46:56

US3362125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User entered '15 Sep 2020 13:10'	System	15 Sep 2020 20:46:56

US3362125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered '36.5' C	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:46:56

US3362125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:46:56

US3362125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:46:56

US3362125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered '70'	(b) (4), (b) (6)	15 Sep 2020 20:46:56

US3362125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User entered 'bpm'	System	15 Sep 2020 20:46:56

US3362125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered '18'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:46:56

US3362125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User entered 'breaths/min'	System	15 Sep 2020 20:46:56

US3362125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered '123'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:46:56

US3362125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User entered 'mmHg'	System	15 Sep 2020 20:46:56

US3362125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered '88'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:46:56

US3362125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User entered 'mmHg'	System	15 Sep 2020 20:46:56

US3362125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	15 Sep 2020 20:46:56

US3362125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:46:56

US3362125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered '15 Sep 2020'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:46:56

US3362125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered '14:33'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:46:56

US3362125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User entered '15 Sep 2020 14:33'	System	15 Sep 2020 20:46:56

US3362125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered '36.5' C	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:46:56

US3362125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:46:56

US3362125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:46:56

US3362125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered '62'	(b) (4), (b) (6)	15 Sep 2020 20:46:56

US3362125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User entered 'bpm'	System	15 Sep 2020 20:46:56

US3362125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered '16'	(b) (4), (b) (6)	15 Sep 2020 20:46:56

US3362125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User entered 'breaths/min'	System	15 Sep 2020 20:46:56

US3362125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered '110'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:46:56

US3362125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User entered 'mmHg'	System	15 Sep 2020 20:46:56

US3362125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered '74'	(b) (4), (b) (6)	15 Sep 2020 20:46:56

US3362125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User entered 'mmHg'	System	15 Sep 2020 20:46:56

US3362125

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:17:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:47:10

US3362125

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:17:16

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered '15 Sep 2020'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:47:10

US3362125

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:16

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:31:59

US3362125

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:16

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 19:31:59

US3362125

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:16

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)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 19:31:59

US3362125

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:16

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User entered 'MRNA-1273 OR PLACEBO'	System	15 Sep 2020 19:31:59

US3362125

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:16

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered '15 Sep 2020'	(b) (4), (b) (6)	15 Sep 2020 19:31:59

US3362125

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:16

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered '14:01'	(b) (4), (b) (6)	15 Sep 2020 19:31:59

US3362125

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:16

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User entered '15 Sep 2020 14:01'	System	15 Sep 2020 19:31:59

US3362125

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:16

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:31:59

US3362125

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:16

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User entered 'ONCE'	System	15 Sep 2020 19:31:59

US3362125

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:16

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User entered 'INTRAMUSCULAR'	System	15 Sep 2020 19:31:59

US3362125

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:17:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:47:39

US3362125

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:17:16

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered '15 Sep 2020'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:47:39

US3362125

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:17:16

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered '13:33'	(b) (4), (b) (6)	15 Sep 2020 20:47:39

US3362125

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:17:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User entered '15 Sep 2020 13:33'	System	15 Sep 2020 20:47:39

US3362125

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:17:16

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered '15 Sep 2020'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:48:02

US3362125

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:17:16

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	15 Sep 2020 20:48:02

US3362125

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:17:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:48:02

US3362125

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:17:16

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered '13:32'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:48:02

US3362125

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:17:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User entered '15 Sep 2020 13:32'	System	15 Sep 2020 20:48:02

US3362125

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:17:16

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	15 Sep 2020 20:48:02

US3362125

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:17:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:48:02

US3362125

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:17:16

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:48:02

US3362125

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:17:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User entered empty.	System	15 Sep 2020 20:48:02

US3362125

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:48:19

US3362125

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User entered 'I'	System	15 Sep 2020 20:48:19

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	15 Sep 2020 19:31:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:17:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-15T14:34:57', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '32e1c42c-5491-4fc4-a2f0-6aa4decc3073' User entered 'Yes (Y)'	System	15 Sep 2020 19:35:28
	System	15 Sep 2020 19:35:28

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:17:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-15T14:35:13', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '32e1c42c-5491-4fc4-a2f0-6aa4decc3073' User entered '97.7'	System	15 Sep 2020 19:35:28
	System	15 Sep 2020 19:35:28

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-15T14:35:18', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '32e1c42c-5491-4fc4-a2f0-6aa4decc3073' User entered 'No (N)'	System	15 Sep 2020 19:35:28
	System	15 Sep 2020 19:35:28

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-15T14:35:23', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '32e1c42c-5491-4fc4-a2f0-6aa4decc3073' User entered '15 Sep 2020 14:35'	System	15 Sep 2020 19:35:28
	System	15 Sep 2020 19:35:28

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '15 Sep 2020 14:21'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '15 Sep 2020 16:51'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	15 Sep 2020 19:31:59
User entered 'Day 1, after vaccination (at home)'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:17:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-15T20:28:07', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '3822c5e6-7676-49cc-9bf0-670e04a5170a' User entered 'Yes (Y)'	System	16 Sep 2020 01:28:28
	System	16 Sep 2020 01:28:28

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:17:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-15T20:28:15', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '3822c5e6-7676-49cc-9bf0-670e04a5170a' User entered '98.6'	System	16 Sep 2020 01:28:28
	System	16 Sep 2020 01:28:28

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-15T20:28:20', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '3822c5e6-7676-49cc-9bf0-670e04a5170a' User entered 'No (N)'	System	16 Sep 2020 01:28:28
	System	16 Sep 2020 01:28:28

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-15T20:28:23', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '3822c5e6-7676-49cc-9bf0-670e04a5170a' User entered '15 Sep 2020 20:28'	System	16 Sep 2020 01:28:28
	System	16 Sep 2020 01:28:28

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '15 Sep 2020 17:46'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	15 Sep 2020 19:31:59
User entered 'Day 2'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:17:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-16T22:46:55', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '02c0c2c3-fe15-45d8-b036-53f1262b423b' User entered 'Yes (Y)'	System	17 Sep 2020 03:47:16
	System	17 Sep 2020 03:47:16

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:17:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-16T22:47:03', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '02c0c2c3-fe15-45d8-b036-53f1262b423b' User entered '96.5'	System	17 Sep 2020 03:47:16
	System	17 Sep 2020 03:47:16

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-16T22:47:08', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '02c0c2c3-fe15-45d8-b036-53f1262b423b' User entered 'No (N)'	System	17 Sep 2020 03:47:16
	System	17 Sep 2020 03:47:16

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-16T22:47:13', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '02c0c2c3-fe15-45d8-b036-53f1262b423b' User entered '16 Sep 2020 22:47'	System	17 Sep 2020 03:47:16
	System	17 Sep 2020 03:47:16

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	15 Sep 2020 19:31:59
User entered 'Day 3'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:17:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-17T23:37:13', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '45eeef67-5f71-4dde-b8bf-ad3ec7f8a90b' User entered 'Yes (Y)'	System	18 Sep 2020 04:37:36
	System	18 Sep 2020 04:37:36

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:17:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-17T23:37:23', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '45eeef67-5f71-4dde-b8bf-ad3ec7f8a90b' User entered '98.2'	System	18 Sep 2020 04:37:36
	System	18 Sep 2020 04:37:36

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-17T23:37:27', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '45eeef67-5f71-4dde-b8bf-ad3ec7f8a90b' User entered 'No (N)'	System	18 Sep 2020 04:37:36
	System	18 Sep 2020 04:37:36

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-17T23:37:33', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '45eeef67-5f71-4dde-b8bf-ad3ec7f8a90b' User entered '17 Sep 2020 23:37'	System	18 Sep 2020 04:37:36
	System	18 Sep 2020 04:37:36

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	15 Sep 2020 19:31:59
User entered 'Day 4'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:17:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-18T20:40:03', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '6bbc2d53-ef25-4e09-bd9b-726249fbbd48' User entered 'Yes (Y)'	System	19 Sep 2020 01:40:21
	System	19 Sep 2020 01:40:21

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:17:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-18T20:40:11', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '6bbc2d53-ef25-4e09-bd9b-726249fbbd48' User entered '97.9'	System	19 Sep 2020 01:40:21
	System	19 Sep 2020 01:40:21

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-18T20:40:15', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '6bbc2d53-ef25-4e09-bd9b-726249fbbd48'	System	19 Sep 2020 01:40:21
User entered 'No (N)'	System	19 Sep 2020 01:40:21

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-18T20:40:17', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '6bbc2d53-ef25-4e09-bd9b-726249fbbd48'	System	19 Sep 2020 01:40:21
User entered '18 Sep 2020 20:40'	System	19 Sep 2020 01:40:21

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '18 Sep 2020 12:00'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '19 Sep 2020 11:59'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	15 Sep 2020 19:31:59
User entered 'Day 5'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:17:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-19T20:28:54', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'a176cbfe-869d-4710-8314-ba920ddce46f' User entered 'Yes (Y)'	System	20 Sep 2020 01:29:11
	System	20 Sep 2020 01:29:11

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:17:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-19T20:29:02', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'a176cbfe-869d-4710-8314-ba920ddce46f' User entered '98.2'	System	20 Sep 2020 01:29:11
	System	20 Sep 2020 01:29:11

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-19T20:29:07', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'a176cbfe-869d-4710-8314-ba920ddce46f' User entered 'No (N)'	System	20 Sep 2020 01:29:11
	System	20 Sep 2020 01:29:11

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-19T20:29:10', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'a176cbfe-869d-4710-8314-ba920ddce46f' User entered '19 Sep 2020 20:29'	System	20 Sep 2020 01:29:11
	System	20 Sep 2020 01:29:11

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '19 Sep 2020 12:00'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '20 Sep 2020 11:59'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	15 Sep 2020 19:31:59
User entered 'Day 6'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:17:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-20T22:38:25', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '1d448830-09b2-45c5-9b78-e1aeb3b3d7ac' User entered 'Yes (Y)'	System	21 Sep 2020 03:38:47
	System	21 Sep 2020 03:38:47

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:17:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-20T22:38:32', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '1d448830-09b2-45c5-9b78-e1aeb3b3d7ac' User entered '97.3'	System	21 Sep 2020 03:38:47
	System	21 Sep 2020 03:38:47

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-20T22:38:38', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '1d448830-09b2-45c5-9b78-e1aeb3b3d7ac' User entered 'No (N)'	System	21 Sep 2020 03:38:47
	System	21 Sep 2020 03:38:47

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-20T22:38:43', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '1d448830-09b2-45c5-9b78-e1aeb3b3d7ac' User entered '20 Sep 2020 22:38'	System	21 Sep 2020 03:38:47
	System	21 Sep 2020 03:38:47

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '20 Sep 2020 12:00'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '21 Sep 2020 11:59'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	15 Sep 2020 19:31:59
User entered 'Day 7'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:17:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-21T21:49:54', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '4084d449-b122-4637-84dc-2e0d02a426af' User entered 'Yes (Y)'	System	22 Sep 2020 02:50:25
	System	22 Sep 2020 02:50:25

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:17:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-21T21:50:00', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '4084d449-b122-4637-84dc-2e0d02a426af' User entered '97.9'	System	22 Sep 2020 02:50:25
	System	22 Sep 2020 02:50:25

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-21T21:50:20', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '4084d449-b122-4637-84dc-2e0d02a426af' User entered 'No (N)'	System	22 Sep 2020 02:50:25
	System	22 Sep 2020 02:50:25

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-21T21:50:23', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '4084d449-b122-4637-84dc-2e0d02a426af' User entered '21 Sep 2020 21:50'	System	22 Sep 2020 02:50:25
	System	22 Sep 2020 02:50:25

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '21 Sep 2020 12:00'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '22 Sep 2020 11:59'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	15 Sep 2020 19:31:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:17:16

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 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-15T14:35:31', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '64be27be-55c7-4b51-98da-f63306883b0a' User entered 'None (1)'	System	15 Sep 2020 19:36:09
	System	15 Sep 2020 19:36:09

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:17:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-15T14:35:51', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '64be27be-55c7-4b51-98da-f63306883b0a' User entered 'No (N)'	System	15 Sep 2020 19:36:09
	System	15 Sep 2020 19:36:09

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-15T14:35:54', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '64be27be-55c7-4b51-98da-f63306883b0a' User entered 'No (N)'	System	15 Sep 2020 19:36:09
	System	15 Sep 2020 19:36:09

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:17:16

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 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-15T14:35:58', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '64be27be-55c7-4b51-98da-f63306883b0a' User entered 'None (1)'	System	15 Sep 2020 19:36:09
	System	15 Sep 2020 19:36:09

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-15T14:36:05', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '64be27be-55c7-4b51-98da-f63306883b0a' User entered '15 Sep 2020 14:36'	System	15 Sep 2020 19:36:09
	System	15 Sep 2020 19:36:09

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '15 Sep 2020 14:21'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '15 Sep 2020 16:51'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	15 Sep 2020 19:31:59
User entered 'Day 1, after vaccination (at home)'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:17:16

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 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-15T20:28:30', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'e356728e-8498-41b4-bbcc-03c9f6bbcdc5' User entered 'None (1)'	System	16 Sep 2020 01:28:47
	System	16 Sep 2020 01:28:47

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:17:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-15T20:28:33', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'e356728e-8498-41b4-bbcc-03c9f6bbcdc5' User entered 'No (N)'	System	16 Sep 2020 01:28:47
	System	16 Sep 2020 01:28:47

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-15T20:28:36', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'e356728e-8498-41b4-bbcc-03c9f6bbcdc5' User entered 'No (N)'	System	16 Sep 2020 01:28:47
	System	16 Sep 2020 01:28:47

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:17:16

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 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-15T20:28:40', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'e356728e-8498-41b4-bbcc-03c9f6bbcdc5'	System	16 Sep 2020 01:28:47
User entered 'None (1)'	System	16 Sep 2020 01:28:47

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-15T20:28:43', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'e356728e-8498-41b4-bbcc-03c9f6bbcdc5' User entered '15 Sep 2020 20:28'	System	16 Sep 2020 01:28:47
	System	16 Sep 2020 01:28:47

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '15 Sep 2020 17:46'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	15 Sep 2020 19:31:59
User entered 'Day 2'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:17:16

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 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-16T22:47:18', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '3d9c7536-987b-4a62-817b-d85b60eedc68'	System	17 Sep 2020 03:47:34
User entered 'None (1)'	System	17 Sep 2020 03:47:34

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:17:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-16T22:47:22', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '3d9c7536-987b-4a62-817b-d85b60eedc68' User entered 'No (N)'	System	17 Sep 2020 03:47:34
	System	17 Sep 2020 03:47:34

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-16T22:47:25', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '3d9c7536-987b-4a62-817b-d85b60eedc68' User entered 'No (N)'	System	17 Sep 2020 03:47:34
	System	17 Sep 2020 03:47:34

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:17:16

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 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-16T22:47:28', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '3d9c7536-987b-4a62-817b-d85b60eedc68'	System	17 Sep 2020 03:47:34
User entered 'None (1)'	System	17 Sep 2020 03:47:34

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-16T22:47:32', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '3d9c7536-987b-4a62-817b-d85b60eedc68' User entered '16 Sep 2020 22:47'	System	17 Sep 2020 03:47:34
	System	17 Sep 2020 03:47:34

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	15 Sep 2020 19:31:59
User entered 'Day 3'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:17:16

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 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-17T23:37:40', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'd2d5d93e-798b-46c9-83d1-61852768454f' User entered 'None (1)'	System	18 Sep 2020 04:37:57
	System	18 Sep 2020 04:37:57

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:17:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-17T23:37:44', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'd2d5d93e-798b-46c9-83d1-61852768454f' User entered 'No (N)'	System	18 Sep 2020 04:37:57
	System	18 Sep 2020 04:37:57

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-17T23:37:47', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'd2d5d93e-798b-46c9-83d1-61852768454f' User entered 'No (N)'	System	18 Sep 2020 04:37:57
	System	18 Sep 2020 04:37:57

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:17:16

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 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-17T23:37:53', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'd2d5d93e-798b-46c9-83d1-61852768454f' User entered 'None (1)'	System	18 Sep 2020 04:37:57
	System	18 Sep 2020 04:37:57

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-17T23:37:56', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'd2d5d93e-798b-46c9-83d1-61852768454f' User entered '17 Sep 2020 23:37'	System	18 Sep 2020 04:37:57
	System	18 Sep 2020 04:37:57

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	15 Sep 2020 19:31:59
User entered 'Day 4'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:17:16

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 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-18T20:40:22', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'adb10117-6296-4997-ac39-62e98539ec44'	System	19 Sep 2020 01:40:38
User entered 'None (1)'	System	19 Sep 2020 01:40:38

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:17:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-18T20:40:25', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'adb10117-6296-4997-ac39-62e98539ec44' User entered 'No (N)'	System	19 Sep 2020 01:40:38
	System	19 Sep 2020 01:40:38

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-18T20:40:29', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'adb10117-6296-4997-ac39-62e98539ec44' User entered 'No (N)'	System	19 Sep 2020 01:40:38
	System	19 Sep 2020 01:40:38

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:17:16

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 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-18T20:40:32', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'adb10117-6296-4997-ac39-62e98539ec44'	System	19 Sep 2020 01:40:38
User entered 'None (1)'	System	19 Sep 2020 01:40:38

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-18T20:40:35', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'adb10117-6296-4997-ac39-62e98539ec44'	System	19 Sep 2020 01:40:38
User entered '18 Sep 2020 20:40'	System	19 Sep 2020 01:40:38

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '18 Sep 2020 12:00'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '19 Sep 2020 11:59'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	15 Sep 2020 19:31:59
User entered 'Day 5'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:17:16

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 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-19T20:28:30', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '4b2b8999-2d52-4a8a-889e-bd8118697bd4'	System	20 Sep 2020 01:28:49
User entered 'None (1)'	System	20 Sep 2020 01:28:49

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:17:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-19T20:28:34', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '4b2b8999-2d52-4a8a-889e-bd8118697bd4'	System	20 Sep 2020 01:28:49
User entered 'No (N)'	System	20 Sep 2020 01:28:49

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-19T20:28:39', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '4b2b8999-2d52-4a8a-889e-bd8118697bd4' User entered 'No (N)'	System	20 Sep 2020 01:28:49
	System	20 Sep 2020 01:28:49

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:17:16

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 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-19T20:28:41', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '4b2b8999-2d52-4a8a-889e-bd8118697bd4'	System	20 Sep 2020 01:28:49
User entered 'None (1)'	System	20 Sep 2020 01:28:49

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-19T20:28:45', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '4b2b8999-2d52-4a8a-889e-bd8118697bd4' User entered '19 Sep 2020 20:28'	System	20 Sep 2020 01:28:49
	System	20 Sep 2020 01:28:49

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '19 Sep 2020 12:00'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '20 Sep 2020 11:59'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	15 Sep 2020 19:31:59
User entered 'Day 6'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:17:16

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 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-20T22:38:49', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '3cd3dd07-fc1c-43b2-abe4-a611556b1d63' User entered 'None (1)'	System	21 Sep 2020 03:39:07
	System	21 Sep 2020 03:39:07

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:17:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-20T22:38:53', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '3cd3dd07-fc1c-43b2-abe4-a611556b1d63' User entered 'No (N)'	System	21 Sep 2020 03:39:07
	System	21 Sep 2020 03:39:07

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-20T22:38:56', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '3cd3dd07-fc1c-43b2-abe4-a611556b1d63' User entered 'No (N)'	System	21 Sep 2020 03:39:07
	System	21 Sep 2020 03:39:07

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:17:16

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 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-20T22:38:59', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '3cd3dd07-fc1c-43b2-abe4-a611556b1d63' User entered 'None (1)'	System	21 Sep 2020 03:39:07
	System	21 Sep 2020 03:39:07

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-20T22:39:02', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '3cd3dd07-fc1c-43b2-abe4-a611556b1d63' User entered '20 Sep 2020 22:39'	System	21 Sep 2020 03:39:07
	System	21 Sep 2020 03:39:07

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '20 Sep 2020 12:00'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '21 Sep 2020 11:59'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	15 Sep 2020 19:31:59
User entered 'Day 7'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:17:16

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 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-21T21:50:28', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '1636ec81-01ad-4050-86a7-96e3af254dd3'	System	22 Sep 2020 02:50:43
User entered 'None (1)'	System	22 Sep 2020 02:50:43

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:17:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-21T21:50:32', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '1636ec81-01ad-4050-86a7-96e3af254dd3' User entered 'No (N)'	System	22 Sep 2020 02:50:43
	System	22 Sep 2020 02:50:43

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-21T21:50:35', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '1636ec81-01ad-4050-86a7-96e3af254dd3' User entered 'No (N)'	System	22 Sep 2020 02:50:43
	System	22 Sep 2020 02:50:43

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:17:16

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 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-21T21:50:38', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '1636ec81-01ad-4050-86a7-96e3af254dd3' User entered 'None (1)'	System	22 Sep 2020 02:50:43
	System	22 Sep 2020 02:50:43

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-21T21:50:41', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '1636ec81-01ad-4050-86a7-96e3af254dd3'	System	22 Sep 2020 02:50:43
User entered '21 Sep 2020 21:50'	System	22 Sep 2020 02:50:43

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '21 Sep 2020 12:00'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '22 Sep 2020 11:59'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	15 Sep 2020 19:31:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:17:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-15T14:36:13', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'abb1848b-d31c-4c84-aa95-40ae7a268156' User entered 'None (0)'	System	15 Sep 2020 19:36:31
	System	15 Sep 2020 19:36:31

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:17:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-15T14:36:15', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'abb1848b-d31c-4c84-aa95-40ae7a268156' User entered 'None (0)'	System	15 Sep 2020 19:36:31
	System	15 Sep 2020 19:36:31

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:17:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-15T14:36:18', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'abb1848b-d31c-4c84-aa95-40ae7a268156' User entered 'None (0)'	System	15 Sep 2020 19:36:31
	System	15 Sep 2020 19:36:31

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:17:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-15T14:36:20', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'abb1848b-d31c-4c84-aa95-40ae7a268156' User entered 'None (0)'	System	15 Sep 2020 19:36:31
	System	15 Sep 2020 19:36:31

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:17:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-15T14:36:22', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'abb1848b-d31c-4c84-aa95-40ae7a268156' User entered 'None (0)'	System	15 Sep 2020 19:36:31
	System	15 Sep 2020 19:36:31

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:17:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-15T14:36:24', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'abb1848b-d31c-4c84-aa95-40ae7a268156' User entered 'None (0)'	System	15 Sep 2020 19:36:31
	System	15 Sep 2020 19:36:31

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:17:16

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 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-15T14:36:27', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'abb1848b-d31c-4c84-aa95-40ae7a268156' User entered 'No (N)'	System	15 Sep 2020 19:36:31
	System	15 Sep 2020 19:36:31

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:17:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-15T14:36:30', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'abb1848b-d31c-4c84-aa95-40ae7a268156' User entered '15 Sep 2020 14:36'	System	15 Sep 2020 19:36:31
	System	15 Sep 2020 19:36:31

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '15 Sep 2020 14:21'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '15 Sep 2020 16:51'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	15 Sep 2020 19:31:59
User entered 'Day 1, after vaccination (at home)'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:17:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-15T20:28:48', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '096c818c-8bbe-4a3f-87df-4e1e2709bea6' User entered 'None (0)'	System	16 Sep 2020 01:29:12
	System	16 Sep 2020 01:29:12

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:17:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-15T20:28:51', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '096c818c-8bbe-4a3f-87df-4e1e2709bea6' User entered 'None (0)'	System	16 Sep 2020 01:29:12
	System	16 Sep 2020 01:29:12

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:17:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-15T20:28:54', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '096c818c-8bbe-4a3f-87df-4e1e2709bea6' User entered 'None (0)'	System	16 Sep 2020 01:29:12
	System	16 Sep 2020 01:29:12

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:17:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-15T20:28:56', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '096c818c-8bbe-4a3f-87df-4e1e2709bea6' User entered 'None (0)'	System	16 Sep 2020 01:29:12
	System	16 Sep 2020 01:29:12

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:17:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-15T20:28:59', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '096c818c-8bbe-4a3f-87df-4e1e2709bea6' User entered 'None (0)'	System	16 Sep 2020 01:29:12
	System	16 Sep 2020 01:29:12

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:17:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-15T20:29:01', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '096c818c-8bbe-4a3f-87df-4e1e2709bea6' User entered 'None (0)'	System	16 Sep 2020 01:29:12
	System	16 Sep 2020 01:29:12

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:17:16

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 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-15T20:29:06', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '096c818c-8bbe-4a3f-87df-4e1e2709bea6' User entered 'No (N)'	System	16 Sep 2020 01:29:12
	System	16 Sep 2020 01:29:12

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:17:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-15T20:29:09', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '096c818c-8bbe-4a3f-87df-4e1e2709bea6' User entered '15 Sep 2020 20:29'	System	16 Sep 2020 01:29:12
	System	16 Sep 2020 01:29:12

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '15 Sep 2020 17:46'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	15 Sep 2020 19:31:59
User entered 'Day 2'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:17:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-16T22:47:37', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '7dc71b9f-53c3-49ec-9e78-2be824590bfc' User entered 'None (0)'	System	17 Sep 2020 03:48:01
	System	17 Sep 2020 03:48:01

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:17:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-16T22:47:40', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '7dc71b9f-53c3-49ec-9e78-2be824590bfc' User entered 'None (0)'	System	17 Sep 2020 03:48:01
	System	17 Sep 2020 03:48:01

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:17:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-16T22:47:42', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '7dc71b9f-53c3-49ec-9e78-2be824590bfc' User entered 'None (0)'	System	17 Sep 2020 03:48:01
	System	17 Sep 2020 03:48:01

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:17:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-16T22:47:45', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '7dc71b9f-53c3-49ec-9e78-2be824590bfc' User entered 'None (0)'	System	17 Sep 2020 03:48:01
	System	17 Sep 2020 03:48:01

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:17:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-16T22:47:48', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '7dc71b9f-53c3-49ec-9e78-2be824590bfc' User entered 'None (0)'	System	17 Sep 2020 03:48:01
	System	17 Sep 2020 03:48:01

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:17:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-16T22:47:50', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '7dc71b9f-53c3-49ec-9e78-2be824590bfc' User entered 'None (0)'	System	17 Sep 2020 03:48:01
	System	17 Sep 2020 03:48:01

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:17:16

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 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-16T22:47:54', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '7dc71b9f-53c3-49ec-9e78-2be824590bfc' User entered 'No (N)'	System	17 Sep 2020 03:48:01
	System	17 Sep 2020 03:48:01

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:17:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-16T22:47:57', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '7dc71b9f-53c3-49ec-9e78-2be824590bfc' User entered '16 Sep 2020 22:47'	System	17 Sep 2020 03:48:01
	System	17 Sep 2020 03:48:01

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	15 Sep 2020 19:31:59
User entered 'Day 3'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:17:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-17T23:38:02', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '292960c2-07c6-468a-9eaa-4ccf6ff558cc' User entered 'None (0)'	System	18 Sep 2020 04:38:23
	System	18 Sep 2020 04:38:23

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:17:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-17T23:38:04', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '292960c2-07c6-468a-9eaa-4ccf6ff558cc' User entered 'None (0)'	System	18 Sep 2020 04:38:23
	System	18 Sep 2020 04:38:23

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:17:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-17T23:38:07', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '292960c2-07c6-468a-9eaa-4ccf6ff558cc' User entered 'None (0)'	System	18 Sep 2020 04:38:23
	System	18 Sep 2020 04:38:23

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:17:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-17T23:38:09', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '292960c2-07c6-468a-9eaa-4ccf6ff558cc' User entered 'None (0)'	System	18 Sep 2020 04:38:23
	System	18 Sep 2020 04:38:23

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:17:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-17T23:38:12', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '292960c2-07c6-468a-9eaa-4ccf6ff558cc' User entered 'None (0)'	System	18 Sep 2020 04:38:23
	System	18 Sep 2020 04:38:23

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:17:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-17T23:38:14', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '292960c2-07c6-468a-9eaa-4ccf6ff558cc' User entered 'None (0)'	System	18 Sep 2020 04:38:23
	System	18 Sep 2020 04:38:23

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:17:16

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 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-17T23:38:18', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '292960c2-07c6-468a-9eaa-4ccf6ff558cc' User entered 'No (N)'	System	18 Sep 2020 04:38:23
	System	18 Sep 2020 04:38:23

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:17:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-17T23:38:21', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '292960c2-07c6-468a-9eaa-4ccf6ff558cc' User entered '17 Sep 2020 23:38'	System	18 Sep 2020 04:38:23
	System	18 Sep 2020 04:38:23

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	15 Sep 2020 19:31:59
User entered 'Day 4'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:17:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-18T20:40:41', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '7a6759fd-366e-4147-bd37-f2e838a1ae11' User entered 'None (0)'	System	19 Sep 2020 01:41:00
	System	19 Sep 2020 01:41:00

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:17:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-18T20:40:43', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '7a6759fd-366e-4147-bd37-f2e838a1ae11' User entered 'None (0)'	System	19 Sep 2020 01:41:00
	System	19 Sep 2020 01:41:00

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:17:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-18T20:40:46', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '7a6759fd-366e-4147-bd37-f2e838a1ae11' User entered 'None (0)'	System	19 Sep 2020 01:41:00
	System	19 Sep 2020 01:41:00

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:17:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-18T20:40:48', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '7a6759fd-366e-4147-bd37-f2e838a1ae11' User entered 'None (0)'	System	19 Sep 2020 01:41:00
	System	19 Sep 2020 01:41:00

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:17:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-18T20:40:50', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '7a6759fd-366e-4147-bd37-f2e838a1ae11' User entered 'None (0)'	System	19 Sep 2020 01:41:00
	System	19 Sep 2020 01:41:00

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:17:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-18T20:40:53', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '7a6759fd-366e-4147-bd37-f2e838a1ae11' User entered 'None (0)'	System	19 Sep 2020 01:41:00
	System	19 Sep 2020 01:41:00

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:17:16

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 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-18T20:40:55', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '7a6759fd-366e-4147-bd37-f2e838a1ae11' User entered 'No (N)'	System	19 Sep 2020 01:41:00
	System	19 Sep 2020 01:41:00

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:17:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-18T20:40:58', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '7a6759fd-366e-4147-bd37-f2e838a1ae11'	System	19 Sep 2020 01:41:00
User entered '18 Sep 2020 20:40'	System	19 Sep 2020 01:41:00

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '18 Sep 2020 12:00'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '19 Sep 2020 11:59'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	15 Sep 2020 19:31:59
User entered 'Day 5'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:17:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-19T20:29:15', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '048088eb-4824-4510-8ec6-f706c82d442d' User entered 'None (0)'	System	20 Sep 2020 01:29:31
	System	20 Sep 2020 01:29:31

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:17:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-19T20:29:17', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '048088eb-4824-4510-8ec6-f706c82d442d' User entered 'None (0)'	System	20 Sep 2020 01:29:31
	System	20 Sep 2020 01:29:31

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:17:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-19T20:29:18', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '048088eb-4824-4510-8ec6-f706c82d442d' User entered 'None (0)'	System	20 Sep 2020 01:29:31
	System	20 Sep 2020 01:29:31

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:17:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-19T20:29:20', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '048088eb-4824-4510-8ec6-f706c82d442d' User entered 'None (0)'	System	20 Sep 2020 01:29:31
	System	20 Sep 2020 01:29:31

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:17:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-19T20:29:22', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '048088eb-4824-4510-8ec6-f706c82d442d' User entered 'None (0)'	System	20 Sep 2020 01:29:31
	System	20 Sep 2020 01:29:31

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:17:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-19T20:29:24', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '048088eb-4824-4510-8ec6-f706c82d442d' User entered 'None (0)'	System	20 Sep 2020 01:29:31
	System	20 Sep 2020 01:29:31

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:17:16

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 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-19T20:29:26', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '048088eb-4824-4510-8ec6-f706c82d442d' User entered 'No (N)'	System	20 Sep 2020 01:29:31
	System	20 Sep 2020 01:29:31

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:17:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-19T20:29:28', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '048088eb-4824-4510-8ec6-f706c82d442d' User entered '19 Sep 2020 20:29'	System	20 Sep 2020 01:29:31
	System	20 Sep 2020 01:29:31

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '19 Sep 2020 12:00'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '20 Sep 2020 11:59'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	15 Sep 2020 19:31:59
User entered 'Day 6'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:17:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-20T22:39:07', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '7e6d1a8a-ddb9-4cce-8d08-124725014ac4' User entered 'None (0)'	System	21 Sep 2020 03:39:32
	System	21 Sep 2020 03:39:32

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:17:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-20T22:39:10', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '7e6d1a8a-ddb9-4cce-8d08-124725014ac4' User entered 'None (0)'	System	21 Sep 2020 03:39:32
	System	21 Sep 2020 03:39:32

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:17:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-20T22:39:12', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '7e6d1a8a-ddb9-4cce-8d08-124725014ac4' User entered 'None (0)'	System	21 Sep 2020 03:39:32
	System	21 Sep 2020 03:39:32

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:17:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-20T22:39:15', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '7e6d1a8a-ddb9-4cce-8d08-124725014ac4' User entered 'None (0)'	System	21 Sep 2020 03:39:32
	System	21 Sep 2020 03:39:32

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:17:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-20T22:39:17', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '7e6d1a8a-ddb9-4cce-8d08-124725014ac4' User entered 'None (0)'	System	21 Sep 2020 03:39:32
	System	21 Sep 2020 03:39:32

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:17:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-20T22:39:20', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '7e6d1a8a-ddb9-4cce-8d08-124725014ac4' User entered 'None (0)'	System	21 Sep 2020 03:39:32
	System	21 Sep 2020 03:39:32

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:17:16

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 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-20T22:39:24', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '7e6d1a8a-ddb9-4cce-8d08-124725014ac4' User entered 'No (N)'	System	21 Sep 2020 03:39:32
	System	21 Sep 2020 03:39:32

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:17:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-20T22:39:27', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '7e6d1a8a-ddb9-4cce-8d08-124725014ac4' User entered '20 Sep 2020 22:39'	System	21 Sep 2020 03:39:32
	System	21 Sep 2020 03:39:32

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '20 Sep 2020 12:00'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '21 Sep 2020 11:59'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	15 Sep 2020 19:31:59
User entered 'Day 7'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:17:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-21T21:50:46', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '4d6242d5-66ef-4872-83e2-4450beb0cded' User entered 'None (0)'	System	22 Sep 2020 02:51:10
	System	22 Sep 2020 02:51:10

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:17:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-21T21:50:49', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '4d6242d5-66ef-4872-83e2-4450beb0cded' User entered 'None (0)'	System	22 Sep 2020 02:51:10
	System	22 Sep 2020 02:51:10

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:17:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-21T21:50:52', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '4d6242d5-66ef-4872-83e2-4450beb0cded' User entered 'None (0)'	System	22 Sep 2020 02:51:10
	System	22 Sep 2020 02:51:10

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:17:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-21T21:50:54', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '4d6242d5-66ef-4872-83e2-4450beb0cded' User entered 'None (0)'	System	22 Sep 2020 02:51:10
	System	22 Sep 2020 02:51:10

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:17:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-21T21:50:57', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '4d6242d5-66ef-4872-83e2-4450beb0cded' User entered 'None (0)'	System	22 Sep 2020 02:51:10
	System	22 Sep 2020 02:51:10

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:17:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-21T21:51:00', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '4d6242d5-66ef-4872-83e2-4450beb0cded' User entered 'None (0)'	System	22 Sep 2020 02:51:10
	System	22 Sep 2020 02:51:10

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:17:16

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 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-21T21:51:04', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '4d6242d5-66ef-4872-83e2-4450beb0cded' User entered 'No (N)'	System	22 Sep 2020 02:51:10
	System	22 Sep 2020 02:51:10

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:17:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-09-21T21:51:07', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '4d6242d5-66ef-4872-83e2-4450beb0cded' User entered '21 Sep 2020 21:51'	System	22 Sep 2020 02:51:10
	System	22 Sep 2020 02:51:10

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '21 Sep 2020 12:00'	System	15 Sep 2020 19:31:59

US3362125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
User entered '22 Sep 2020 11:59'	System	15 Sep 2020 19:31:59

US3362125

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 18:18:47

US3362125

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:31
User entered '22 Sep 2020'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 18:18:47

US3362125

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:31
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 18:18:47

US3362125

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:31
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 18:18:47

US3362125

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 18:18:52

US3362125

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User entered 'I'	System	22 Sep 2020 18:18:52

US3362125

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 17:35:32

US3362125

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:31
User entered '29 Sep 2020'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 17:35:32

US3362125

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:31
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 17:35:32

US3362125

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:31
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 17:35:32

US3362125

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 17:35:37

US3362125

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User entered 'I'	System	29 Sep 2020 17:35:37

US3362125

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 17:17:34

US3362125

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered '06 Oct 2020'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 17:17:34

US3362125

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 17:17:34

US3362125

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 17:17:34

US3362125

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 17:17:39

US3362125

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User entered 'I'	System	06 Oct 2020 17:17:39

US3362125

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:17:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:23:14

US3362125

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered '13 Oct 2020'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:23:14

US3362125

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:17:16

[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 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:23:14

US3362125

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:17:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User entered 'VISIT3'	System	13 Oct 2020 19:23:14

US3362125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:23:52

US3362125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered '13 Oct 2020'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:23:52

US3362125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered '12:55'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:23:52

US3362125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User entered '13 Oct 2020 12:55'	System	13 Oct 2020 19:23:52

US3362125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered '36.7' C	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:23:52

US3362125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:23:52

US3362125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:23:52

US3362125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered '73'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:23:52

US3362125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User entered 'bpm'	System	13 Oct 2020 19:23:52

US3362125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered '16'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:23:52

US3362125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User entered 'breaths/min'	System	13 Oct 2020 19:23:52

US3362125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered '127'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:23:52

US3362125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User entered 'mmHg'	System	13 Oct 2020 19:23:52

US3362125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered '80'	(b) (4), (b) (6)	13 Oct 2020 19:23:52

US3362125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User entered 'mmHg'	System	13 Oct 2020 19:23:52

US3362125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13

US3362125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13

US3362125

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:17:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:24:01

US3362125

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:17:16

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered '13 Oct 2020'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:24:01

US3362125

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:17:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:24:28

US3362125

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:17:16

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered '13 Oct 2020'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:24:28

US3362125

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:17:16

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered '13:05'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:24:28

US3362125

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:17:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User entered '13 Oct 2020 13:05'	System	13 Oct 2020 19:24:28

US3362125

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:04:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:24:33

US3362125

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User entered 'I'	System	13 Oct 2020 19:24:33

US3362125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	13 Aug 2020 16:38:28
User entered 'Day 64'	System	13 Aug 2020 16:38:28

US3362125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-10-13T22:45:27', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'b1d3d62a-a3a4-4ca5-878c-006d6d21dcda' User entered 'No (N)'	System	14 Oct 2020 03:45:43
	System	14 Oct 2020 03:45:43

US3362125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

Have you been exposed to someone with 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 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-10-13T22:45:17', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'b1d3d62a-a3a4-4ca5-878c-006d6d21dcda' User entered 'No (N)'	System	14 Oct 2020 03:45:43
	System	14 Oct 2020 03:45:43

US3362125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-10-13T22:45:38', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'b1d3d62a-a3a4-4ca5-878c-006d6d21dcda' User entered '13 Oct 2020 22:45:38'	System	14 Oct 2020 03:45:43
	System	14 Oct 2020 03:45:43

US3362125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	13 Aug 2020 16:38:28
User entered '13 Oct 2020 00:01'	System	13 Aug 2020 16:38:28

US3362125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	13 Aug 2020 16:38:28
User entered '17 Oct 2020 23:59'	System	13 Aug 2020 16:38:28

US3362125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	13 Aug 2020 16:38:28
User entered 'Day 71'	System	13 Aug 2020 16:38:28

US3362125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-10-20T07:51:33', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '81603acf-ae3a-4f2e-91bb-f5b6b0442959'	System	20 Oct 2020 12:51:57
User entered 'No (N)'	System	20 Oct 2020 12:51:57

US3362125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

Have you been exposed to someone with 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 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-10-20T07:51:44', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '81603acf-ae3a-4f2e-91bb-f5b6b0442959'	System	20 Oct 2020 12:51:57
User entered 'No (N)'	System	20 Oct 2020 12:51:57

US3362125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-10-20T07:51:53', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '81603acf-ae3a-4f2e-91bb-f5b6b0442959' User entered '20 Oct 2020 07:51:53'	System	20 Oct 2020 12:51:57
	System	20 Oct 2020 12:51:57

US3362125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	13 Aug 2020 16:38:28
User entered '20 Oct 2020 00:01'	System	13 Aug 2020 16:38:28

US3362125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	13 Aug 2020 16:38:28
User entered '24 Oct 2020 23:59'	System	13 Aug 2020 16:38:28

US3362125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	13 Aug 2020 16:38:28
User entered 'Day 78'	System	13 Aug 2020 16:38:28

US3362125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-10-27T07:03:55', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '9632c7bf-c064-4f2d-aba7-96ce5c219411' User entered 'No (N)'	System	27 Oct 2020 12:04:14
	System	27 Oct 2020 12:04:14

US3362125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

Have you been exposed to someone with 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 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-10-27T07:04:03', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '9632c7bf-c064-4f2d-aba7-96ce5c219411'	System	27 Oct 2020 12:04:14
User entered 'No (N)'	System	27 Oct 2020 12:04:14

US3362125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-10-27T07:04:11', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '9632c7bf-c064-4f2d-aba7-96ce5c219411' User entered '27 Oct 2020 07:04:11'	System	27 Oct 2020 12:04:14
	System	27 Oct 2020 12:04:14

US3362125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	13 Aug 2020 16:38:28
User entered '27 Oct 2020 00:01'	System	13 Aug 2020 16:38:28

US3362125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	13 Aug 2020 16:38:28
User entered '31 Oct 2020 23:59'	System	13 Aug 2020 16:38:28

US3362125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	13 Aug 2020 16:38:28
User entered 'Day 92'	System	13 Aug 2020 16:38:28

US3362125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-11-10T09:26:12', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '79682c4a-ce38-4a0e-a344-38dc37ff801a' User entered 'Yes (Y)'	System	10 Nov 2020 15:28:48
	System	10 Nov 2020 15:28:48

US3362125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

Have you been exposed to someone with 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 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-11-10T09:26:24', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '79682c4a-ce38-4a0e-a344-38dc37ff801a'	System	10 Nov 2020 15:28:48
User entered 'No (N)'	System	10 Nov 2020 15:28:48

US3362125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-11-10T09:26:29', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '79682c4a-ce38-4a0e-a344-38dc37ff801a' User entered 'Yes (Y)'	System	10 Nov 2020 15:28:48
	System	10 Nov 2020 15:28:48

US3362125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-11-10T09:27:16', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '79682c4a-ce38-4a0e-a344-38dc37ff801a' User entered '1'	System	10 Nov 2020 15:28:48
	System	10 Nov 2020 15:28:48

US3362125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-11-10T09:27:16', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '79682c4a-ce38-4a0e-a344-38dc37ff801a' User entered '1'	System	10 Nov 2020 15:28:48
	System	10 Nov 2020 15:28:48

US3362125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-11-10T09:27:16', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '79682c4a-ce38-4a0e-a344-38dc37ff801a' User entered '1'	System	10 Nov 2020 15:28:48
	System	10 Nov 2020 15:28:48

US3362125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-11-10T09:27:16', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '79682c4a-ce38-4a0e-a344-38dc37ff801a' User entered '0'	System	10 Nov 2020 15:28:48
	System	10 Nov 2020 15:28:48

US3362125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-11-10T09:27:16', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '79682c4a-ce38-4a0e-a344-38dc37ff801a' User entered '0'	System	10 Nov 2020 15:28:48
	System	10 Nov 2020 15:28:48

US3362125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-11-10T09:27:16', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '79682c4a-ce38-4a0e-a344-38dc37ff801a' User entered '1'	System	10 Nov 2020 15:28:48
	System	10 Nov 2020 15:28:48

US3362125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-11-10T09:27:16', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '79682c4a-ce38-4a0e-a344-38dc37ff801a' User entered '1'	System	10 Nov 2020 15:28:48
	System	10 Nov 2020 15:28:48

US3362125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-11-10T09:27:16', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '79682c4a-ce38-4a0e-a344-38dc37ff801a' User entered '1'	System	10 Nov 2020 15:28:48
	System	10 Nov 2020 15:28:48

US3362125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-11-10T09:27:16', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '79682c4a-ce38-4a0e-a344-38dc37ff801a' User entered '1'	System	10 Nov 2020 15:28:48
	System	10 Nov 2020 15:28:48

US3362125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-11-10T09:27:16', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '79682c4a-ce38-4a0e-a344-38dc37ff801a' User entered '0'	System	10 Nov 2020 15:28:48
	System	10 Nov 2020 15:28:48

US3362125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-11-10T09:27:16', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '79682c4a-ce38-4a0e-a344-38dc37ff801a' User entered '0'	System	10 Nov 2020 15:28:48
	System	10 Nov 2020 15:28:48

US3362125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-11-10T09:27:16', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '79682c4a-ce38-4a0e-a344-38dc37ff801a' User entered '1'	System	10 Nov 2020 15:28:48
	System	10 Nov 2020 15:28:48

US3362125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-11-10T09:27:16', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '79682c4a-ce38-4a0e-a344-38dc37ff801a' User entered '0'	System	10 Nov 2020 15:28:48
	System	10 Nov 2020 15:28:48

US3362125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-11-10T09:27:16', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '79682c4a-ce38-4a0e-a344-38dc37ff801a' User entered '0'	System	10 Nov 2020 15:28:48
	System	10 Nov 2020 15:28:48

US3362125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-11-10T09:27:16', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '79682c4a-ce38-4a0e-a344-38dc37ff801a' User entered '0'	System	10 Nov 2020 15:28:48
	System	10 Nov 2020 15:28:48

US3362125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-11-10T09:27:16', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '79682c4a-ce38-4a0e-a344-38dc37ff801a' User entered '0'	System	10 Nov 2020 15:28:48
	System	10 Nov 2020 15:28:48

US3362125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-11-10T09:27:16', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '79682c4a-ce38-4a0e-a344-38dc37ff801a' User entered '0'	System	10 Nov 2020 15:28:48
	System	10 Nov 2020 15:28:48

US3362125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Please 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 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-11-10T09:27:25', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '79682c4a-ce38-4a0e-a344-38dc37ff801a'	System	10 Nov 2020 15:28:48
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	10 Nov 2020 15:28:48

US3362125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-11-10T09:28:17', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '79682c4a-ce38-4a0e-a344-38dc37ff801a' User entered 'Yes (Y)'	System	10 Nov 2020 15:28:48
	System	10 Nov 2020 15:28:48

US3362125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Please 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 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-11-10T09:28:24', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '79682c4a-ce38-4a0e-a344-38dc37ff801a'	System	10 Nov 2020 15:28:48
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	10 Nov 2020 15:28:48

US3362125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-11-10T09:28:34', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '79682c4a-ce38-4a0e-a344-38dc37ff801a' User entered '10 Nov 2020 09:28:34'	System	10 Nov 2020 15:28:48
	System	10 Nov 2020 15:28:48

US3362125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	13 Aug 2020 16:38:28
User entered '10 Nov 2020 00:01'	System	13 Aug 2020 16:38:28

US3362125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	13 Aug 2020 16:38:28
User entered '14 Nov 2020 23:59'	System	13 Aug 2020 16:38:28

US3362125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	13 Aug 2020 16:38:28
User entered 'Day 99'	System	13 Aug 2020 16:38:28

US3362125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[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 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-11-17T07:45:39', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '38a5bad7-364d-40ba-95aa-b5f4e7e90dba' User entered 'No (N)'	System	17 Nov 2020 13:45:53
	System	17 Nov 2020 13:45:53

US3362125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

Have you been exposed to someone with 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 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-11-17T07:44:43', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '38a5bad7-364d-40ba-95aa-b5f4e7e90dba' User entered 'No (N)'	System	17 Nov 2020 13:45:53
	System	17 Nov 2020 13:45:53

US3362125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-11-17T07:45:48', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '38a5bad7-364d-40ba-95aa-b5f4e7e90dba' User entered '17 Nov 2020 07:45:48'	System	17 Nov 2020 13:45:53
	System	17 Nov 2020 13:45:53

US3362125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	13 Aug 2020 16:38:28
User entered '17 Nov 2020 00:01'	System	13 Aug 2020 16:38:28

US3362125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:29:02
Data entry locked.	System	13 Aug 2020 16:38:28
User entered '21 Nov 2020 23:59'	System	13 Aug 2020 16:38:28

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[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 (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-11-24T07:47:23', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '1a5c368c-a9b4-4a5a-9eb6-0876c858613b' User entered 'No (N)'	System	24 Nov 2020 13:47:40
	System	24 Nov 2020 13:47:40

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Have you been exposed to someone with 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 (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-11-24T07:47:29', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '1a5c368c-a9b4-4a5a-9eb6-0876c858613b' User entered 'No (N)'	System	24 Nov 2020 13:47:40
	System	24 Nov 2020 13:47:40

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-11-24T07:47:36', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '1a5c368c-a9b4-4a5a-9eb6-0876c858613b' User entered '24 Nov 2020 07:47:36'	System	24 Nov 2020 13:47:40
	System	24 Nov 2020 13:47:40

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[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 (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-11-28T07:44:14', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'e3fa0824-7232-4b61-a0f4-2a6a273bbcc7' User entered 'No (N)'	System	28 Nov 2020 13:44:34
	System	28 Nov 2020 13:44:34

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

Have you been exposed to someone with 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 (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-11-28T07:44:22', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'e3fa0824-7232-4b61-a0f4-2a6a273bbcc7'	System	28 Nov 2020 13:44:34
User entered 'No (N)'	System	28 Nov 2020 13:44:34

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30DDD15D-9E04-4C94-AF78-8D81799C7887)', Time: '2020-11-28T07:44:30', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'e3fa0824-7232-4b61-a0f4-2a6a273bbcc7' User entered '28 Nov 2020 07:44:30'	System	28 Nov 2020 13:44:34
	System	28 Nov 2020 13:44:34

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[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 (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2020-12-09T16:06:09', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '5c0616e6-7472-4257-aa07-e8f9e8292685' User entered 'No (N)'	System	09 Dec 2020 22:06:25
	System	09 Dec 2020 22:06:25

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

Have you been exposed to someone with 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 (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2020-12-09T16:06:17', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '5c0616e6-7472-4257-aa07-e8f9e8292685'	System	09 Dec 2020 22:06:25
User entered 'No (N)'	System	09 Dec 2020 22:06:25

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2020-12-09T16:06:22', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '5c0616e6-7472-4257-aa07-e8f9e8292685' User entered '09 Dec 2020 16:06:22'	System	09 Dec 2020 22:06:25
	System	09 Dec 2020 22:06:25

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[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 (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2020-12-12T15:47:32', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '1e99891f-b7c7-400f-ae06-275f062d9edb' User entered 'No (N)'	System	12 Dec 2020 21:47:48
	System	12 Dec 2020 21:47:48

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

Have you been exposed to someone with 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 (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2020-12-12T15:47:41', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '1e99891f-b7c7-400f-ae06-275f062d9edb' User entered 'No (N)'	System	12 Dec 2020 21:47:48
	System	12 Dec 2020 21:47:48

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2020-12-12T15:47:45', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '1e99891f-b7c7-400f-ae06-275f062d9edb' User entered '12 Dec 2020 15:47:45'	System	12 Dec 2020 21:47:48
	System	12 Dec 2020 21:47:48

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[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 (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2020-12-19T08:52:42', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '5954d79a-9c2c-499a-bd60-f9d44bcbbfb8' User entered 'No (N)'	System	19 Dec 2020 14:52:58
	System	19 Dec 2020 14:52:58

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

Have you been exposed to someone with 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 (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2020-12-19T08:52:50', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '5954d79a-9c2c-499a-bd60-f9d44bcbbfb8' User entered 'No (N)'	System	19 Dec 2020 14:52:58
	System	19 Dec 2020 14:52:58

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2020-12-19T08:52:56', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '5954d79a-9c2c-499a-bd60-f9d44bcbbfb8' User entered '19 Dec 2020 08:52:56'	System	19 Dec 2020 14:52:58
	System	19 Dec 2020 14:52:58

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[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 (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2020-12-26T07:50:46', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '93441632-5a37-4a8e-b29f-22e763ede3aa' User entered 'No (N)'	System	26 Dec 2020 13:51:00
	System	26 Dec 2020 13:51:00

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

Have you been exposed to someone with 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 (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2020-12-26T07:50:53', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '93441632-5a37-4a8e-b29f-22e763ede3aa' User entered 'No (N)'	System	26 Dec 2020 13:51:00
	System	26 Dec 2020 13:51:00

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2020-12-26T07:50:57', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '93441632-5a37-4a8e-b29f-22e763ede3aa' User entered '26 Dec 2020 07:50:57'	System	26 Dec 2020 13:51:00
	System	26 Dec 2020 13:51:00

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[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 (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2021-01-02T20:45:27', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '65a2ced1-cf84-4691-b013-9aefb4c554e1' User entered 'No (N)'	System	03 Jan 2021 02:45:39
	System	03 Jan 2021 02:45:39

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

Have you been exposed to someone with 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 (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2021-01-02T20:45:31', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '65a2ced1-cf84-4691-b013-9aefb4c554e1' User entered 'No (N)'	System	03 Jan 2021 02:45:39

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2021-01-02T20:45:37', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '65a2ced1-cf84-4691-b013-9aefb4c554e1' User entered '02 Jan 2021 20:45:37'	System	03 Jan 2021 02:45:39
	System	03 Jan 2021 02:45:39

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[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 (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2021-01-09T08:13:26', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'b25c24df-5397-4ab8-b718-7de89ee2ff8c' User entered 'No (N)'	System	09 Jan 2021 14:13:43
	System	09 Jan 2021 14:13:43

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Have you been exposed to someone with 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 (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2021-01-09T08:13:31', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'b25c24df-5397-4ab8-b718-7de89ee2ff8c'	System	09 Jan 2021 14:13:43
User entered 'No (N)'	System	09 Jan 2021 14:13:43

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2021-01-09T08:13:40', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'b25c24df-5397-4ab8-b718-7de89ee2ff8c' User entered '09 Jan 2021 08:13:40'	System	09 Jan 2021 14:13:43
	System	09 Jan 2021 14:13:43

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[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 (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2021-01-16T22:16:14', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '7b279851-6f85-4080-b895-d5d96ea2a054'	System	18 Jan 2021 21:13:54
User entered 'No (N)'	System	18 Jan 2021 21:13:54

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

Have you been exposed to someone with 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 (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2021-01-16T22:16:17', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '7b279851-6f85-4080-b895-d5d96ea2a054'	System	18 Jan 2021 21:13:54
User entered 'No (N)'	System	18 Jan 2021 21:13:54

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2021-01-16T22:16:21', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '7b279851-6f85-4080-b895-d5d96ea2a054'	System	18 Jan 2021 21:13:54
User entered '16 Jan 2021 22:16:21'	System	18 Jan 2021 21:13:54

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[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 (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2021-01-23T02:30:14', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'daf57745-cf12-41ca-8915-cdc41ec9c401' User entered 'No (N)'	System	23 Jan 2021 08:30:28
	System	23 Jan 2021 08:30:28

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

Have you been exposed to someone with 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 (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2021-01-23T02:30:19', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'daf57745-cf12-41ca-8915-cdc41ec9c401'	System	23 Jan 2021 08:30:28
User entered 'No (N)'	System	23 Jan 2021 08:30:28

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2021-01-23T02:30:25', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'daf57745-cf12-41ca-8915-cdc41ec9c401' User entered '23 Jan 2021 02:30:25'	System	23 Jan 2021 08:30:28
	System	23 Jan 2021 08:30:28

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[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 (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2021-01-30T07:31:05', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'c32ead4b-561b-4ab2-813c-5350f0059239' User entered 'No (N)'	System	30 Jan 2021 11:31:15
	System	30 Jan 2021 11:31:15

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

Have you been exposed to someone with 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 (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2021-01-30T07:31:09', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'c32ead4b-561b-4ab2-813c-5350f0059239' User entered 'No (N)'	System	30 Jan 2021 11:31:15
	System	30 Jan 2021 11:31:15

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2021-01-30T07:31:14', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'c32ead4b-561b-4ab2-813c-5350f0059239' User entered '30 Jan 2021 07:31:14'	System	30 Jan 2021 11:31:15
	System	30 Jan 2021 11:31:15

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[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 (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2021-02-06T06:55:27', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'f6bb4e97-4942-4772-b966-b4f39cf1d5cc' User entered 'No (N)'	System	06 Feb 2021 10:55:45
	System	06 Feb 2021 10:55:45

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

Have you been exposed to someone with 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 (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2021-02-06T06:55:37', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'f6bb4e97-4942-4772-b966-b4f39cf1d5cc' User entered 'No (N)'	System	06 Feb 2021 10:55:45

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2021-02-06T06:55:43', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'f6bb4e97-4942-4772-b966-b4f39cf1d5cc' User entered '06 Feb 2021 06:55:43'	System	06 Feb 2021 10:55:45
	System	06 Feb 2021 10:55:45

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[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 (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2021-02-13T08:58:03', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'bc3590ff-7316-4e7c-be7a-bf90cf975be6' User entered 'No (N)'	System	13 Feb 2021 14:58:30
	System	13 Feb 2021 14:58:30

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

Have you been exposed to someone with 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 (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2021-02-13T08:58:15', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'bc3590ff-7316-4e7c-be7a-bf90cf975be6' User entered 'No (N)'	System	13 Feb 2021 14:58:30
	System	13 Feb 2021 14:58:30

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2021-02-13T08:58:25', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'bc3590ff-7316-4e7c-be7a-bf90cf975be6'	System	13 Feb 2021 14:58:30
User entered '13 Feb 2021 08:58:25'	System	13 Feb 2021 14:58:30

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[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 (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2021-02-20T08:26:32', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '45ce57c7-2163-4bfb-90aa-6a6fbae8d1c9' User entered 'No (N)'	System	20 Feb 2021 14:26:49
	System	20 Feb 2021 14:26:49

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

Have you been exposed to someone with 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 (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2021-02-20T08:26:38', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '45ce57c7-2163-4bfb-90aa-6a6fbae8d1c9' User entered 'No (N)'	System	20 Feb 2021 14:26:49

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2021-02-20T08:26:46', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '45ce57c7-2163-4bfb-90aa-6a6fbae8d1c9' User entered '20 Feb 2021 08:26:46'	System	20 Feb 2021 14:26:49
	System	20 Feb 2021 14:26:49

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[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 (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2021-02-27T07:58:20-06:00', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '2e2cbbe0-d08f-4201-aeel-0acab7e9af2e' User entered 'No (N)'	System	27 Feb 2021 13:58:36
	System	27 Feb 2021 13:58:36

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

Have you been exposed to someone with 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 (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2021-02-27T07:58:30-06:00', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '2e2cbbe0-d08f-4201-aeel-0acab7e9af2e'	System	27 Feb 2021 13:58:36
User entered 'No (N)'	System	27 Feb 2021 13:58:36

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2021-02-27T07:58:34-06:00', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '2e2cbbe0-d08f-4201-aeel-0acab7e9af2e'	System	27 Feb 2021 13:58:36
User entered '27 Feb 2021 13:58:34'	System	27 Feb 2021 13:58:36

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[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 (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2021-03-06T06:44:02-06:00', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'be03bfe8-8d39-4461-ac16-f50e49a37c17'	System	06 Mar 2021 12:44:14
User entered 'No (N)'	System	06 Mar 2021 12:44:14

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

Have you been exposed to someone with 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 (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2021-03-06T06:44:06-06:00', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'be03bfe8-8d39-4461-ac16-f50e49a37c17'	System	06 Mar 2021 12:44:14
User entered 'No (N)'	System	06 Mar 2021 12:44:14

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2021-03-06T06:44:11-06:00', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'be03bfe8-8d39-4461-ac16-f50e49a37c17'	System	06 Mar 2021 12:44:14
User entered '06 Mar 2021 06:44:11'	System	06 Mar 2021 12:44:14

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[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 (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2021-03-13T08:33:13-06:00', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'fb134bb6-e290-41bd-9f4b-1b1a7deff765'	System	13 Mar 2021 14:33:23
User entered 'No (N)'	System	13 Mar 2021 14:33:23

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

Have you been exposed to someone with 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 (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2021-03-13T08:33:17-06:00', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'fb134bb6-e290-41bd-9f4b-1b1a7deff765'	System	13 Mar 2021 14:33:23
User entered 'No (N)'	System	13 Mar 2021 14:33:23

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2021-03-13T08:33:20-06:00', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'fb134bb6-e290-41bd-9f4b-1b1a7deff765'	System	13 Mar 2021 14:33:23
User entered '13 Mar 2021 08:33:20'	System	13 Mar 2021 14:33:23

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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 (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2021-03-22T07:18:27-05:00', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '6d02c45a-1043-4d1e-9f7c-b18d1eeb8ba9' User entered 'Yes (Y)'	System	22 Mar 2021 12:19:23
	System	22 Mar 2021 12:19:23

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

Have you been exposed to someone with 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 (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2021-03-22T07:18:34-05:00', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '6d02c45a-1043-4d1e-9f7c-b18d1eeb8ba9'	System	22 Mar 2021 12:19:23
User entered 'No (N)'	System	22 Mar 2021 12:19:23

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2021-03-22T07:18:46-05:00', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '6d02c45a-1043-4d1e-9f7c-b18d1eeb8ba9' User entered 'No (N)'	System	22 Mar 2021 12:19:23
	System	22 Mar 2021 12:19:23

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2021-03-22T07:18:54-05:00', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '6d02c45a-1043-4d1e-9f7c-b18d1eeb8ba9' User entered 'Yes (Y)'	System	22 Mar 2021 12:19:23
	System	22 Mar 2021 12:19:23

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2021-03-22T07:19:00-05:00', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '6d02c45a-1043-4d1e-9f7c-b18d1eeb8ba9'	System	22 Mar 2021 12:19:23
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	22 Mar 2021 12:19:23

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2021-03-22T07:19:12-05:00', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '6d02c45a-1043-4d1e-9f7c-b18d1eeb8ba9' User entered '22 Mar 2021 07:19:12'	System	22 Mar 2021 12:19:23
	System	22 Mar 2021 12:19:23

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[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 (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2021-03-27T08:38:22-05:00', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'ee940ebf-543d-4e37-a175-4099f85ee2a0'	System	27 Mar 2021 13:38:37
User entered 'No (N)'	System	27 Mar 2021 13:38:37

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

Have you been exposed to someone with 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 (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2021-03-27T08:38:27-05:00', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'ee940ebf-543d-4e37-a175-4099f85ee2a0'	System	27 Mar 2021 13:38:37
User entered 'No (N)'	System	27 Mar 2021 13:38:37

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2021-03-27T08:38:34-05:00', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'ee940ebf-543d-4e37-a175-4099f85ee2a0' User entered '27 Mar 2021 08:38:34'	System	27 Mar 2021 13:38:37
	System	27 Mar 2021 13:38:37

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[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 (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2021-04-03T08:02:36-05:00', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '82422737-41a4-426c-9cdb-487db59a1dad'	System	03 Apr 2021 13:02:49
User entered 'No (N)'	System	03 Apr 2021 13:02:49

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

Have you been exposed to someone with 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 (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2021-04-03T08:02:40-05:00', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '82422737-41a4-426c-9cdb-487db59a1dad'	System	03 Apr 2021 13:02:49
User entered 'No (N)'	System	03 Apr 2021 13:02:49

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2021-04-03T08:02:47-05:00', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '82422737-41a4-426c-9cdb-487db59a1dad'	System	03 Apr 2021 13:02:49
User entered '03 Apr 2021 08:02:47'	System	03 Apr 2021 13:02:49

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[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 (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2021-04-10T09:18:59-05:00', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'd8122ac0-898a-4acc-acfe-4ef2556ec3a5'	System	17 Apr 2021 13:35:35
User entered 'No (N)'	System	17 Apr 2021 13:35:35

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

Have you been exposed to someone with 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 (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2021-04-10T09:19:02-05:00', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'd8122ac0-898a-4acc-acfe-4ef2556ec3a5'	System	17 Apr 2021 13:35:35
User entered 'No (N)'	System	17 Apr 2021 13:35:35

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2021-04-10T09:19:06-05:00', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'd8122ac0-898a-4acc-acfe-4ef2556ec3a5'	System	17 Apr 2021 13:35:35
User entered '10 Apr 2021 09:19:06'	System	17 Apr 2021 13:35:35

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[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 (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2021-04-17T08:35:36-05:00', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '61039c90-d590-46a1-b2d7-ee76dc5f54ed' User entered 'No (N)'	System	17 Apr 2021 13:35:45
	System	17 Apr 2021 13:35:45

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

Have you been exposed to someone with 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 (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2021-04-17T08:35:39-05:00', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '61039c90-d590-46a1-b2d7-ee76dc5f54ed' User entered 'No (N)'	System	17 Apr 2021 13:35:45
	System	17 Apr 2021 13:35:45

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2021-04-17T08:35:43-05:00', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '61039c90-d590-46a1-b2d7-ee76dc5f54ed' User entered '17 Apr 2021 08:35:43'	System	17 Apr 2021 13:35:45
	System	17 Apr 2021 13:35:45

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[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 (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2021-04-26T12:20:40-05:00', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'ea5cf5b8-e44c-40b4-aa8d-0c5beda1ac3c'	System	26 Apr 2021 17:20:49
User entered 'No (N)'	System	26 Apr 2021 17:20:49

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

Have you been exposed to someone with 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 (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2021-04-26T12:20:44-05:00', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'ea5cf5b8-e44c-40b4-aa8d-0c5beda1ac3c'	System	26 Apr 2021 17:20:49
User entered 'No (N)'	System	26 Apr 2021 17:20:49

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2021-04-26T12:20:47-05:00', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: 'ea5cf5b8-e44c-40b4-aa8d-0c5beda1ac3c' User entered '26 Apr 2021 12:20:47'	System	26 Apr 2021 17:20:49
	System	26 Apr 2021 17:20:49

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[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 (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2021-05-01T07:08:53-05:00', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '95676ee8-329c-41cf-b649-7332d3971f1d' User entered 'No (N)'	System	01 May 2021 12:09:05
	System	01 May 2021 12:09:05

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

Have you been exposed to someone with 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 (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2021-05-01T07:08:58-05:00', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '95676ee8-329c-41cf-b649-7332d3971f1d'	System	01 May 2021 12:09:05
User entered 'No (N)'	System	01 May 2021 12:09:05

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2021-05-01T07:09:03-05:00', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '95676ee8-329c-41cf-b649-7332d3971f1d'	System	01 May 2021 12:09:05
User entered '01 May 2021 07:09:03'	System	01 May 2021 12:09:05

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '15 Oct 2022 00:01'	System	19 Nov 2020 06:04:21

US3362125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:04:21
Amendment Manager: User entered '19 Oct 2022 23:59'	System	19 Nov 2020 06:04:21

US3362125

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:17:16

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)	26 Apr 2021 06:20:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2021-02-27T07:58:42-06:00', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '182d425f-c67f-4393-88ac-957e3b6088bb'	System	27 Feb 2021 13:58:52
User entered 'No (N)'	System	27 Feb 2021 13:58:52

US3362125

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:17:16

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:20:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF91E3AD-E451-4B8D-BC91-8C5488F6F8DA)', Time: '2021-02-27T07:58:51-06:00', User OID: 'PatientReportedOutcome (US3362125)', ODM File OID: '182d425f-c67f-4393-88ac-957e3b6088bb' User entered '27 Feb 2021 13:58:51'	System	27 Feb 2021 13:58:52
	System	27 Feb 2021 13:58:52

US3362125

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	06 Mar 2021 04:20:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:53:28

US3362125

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	06 Mar 2021 04:20:52
User entered '9 Nov 2020'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:53:28

US3362125

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	06 Mar 2021 04:20:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:53:28

US3362125

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	06 Mar 2021 04:20:52
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:53:28

US3362125

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User signature succeeded.	Jordan Whatley (b) (4)	06 Mar 2021 04:20:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:53:31

US3362125

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:13
User entered 'I'	System	09 Nov 2020 15:53:31

US3362125

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:44:05
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 20:23:43

US3362125

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:44:05
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered '11 Dec 2020'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 20:23:43

US3362125

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:44:05
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 20:23:43

US3362125

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:44:05
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 20:23:43

US3362125

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:44:05
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 20:23:48

US3362125

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:44:05
User entered 'I'	System	11 Dec 2020 20:23:48

US3362125

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:44:05
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:21:42

US3362125

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:44:05
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:21:42

US3362125

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:44:05
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:21:42

US3362125

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:44:05
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered empty.	(b) (4), (b) (6)	12 Jan 2021 16:21:42

US3362125

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:44:05
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:21:46

US3362125

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:44:05
User entered 'I'	System	12 Jan 2021 16:21:46

US3362125

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:44:05
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:18:06

US3362125

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:44:05
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:18:06

US3362125

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:44:05
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:18:06

US3362125

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:44:05
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:18:06

US3362125

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:44:05
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:18:15

US3362125

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:44:05
User entered 'I'	System	11 Feb 2021 18:18:15

US3362125

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:17:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:47
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User closed query 'Per CDM: Vital signs info missing. Please complete this section of the eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:45:01
Query 'Per CDM: Vital signs info missing. Please complete this section of the eCRF. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 21:47:14
User opened query 'Per CDM: Vital signs info missing. Please complete this section of the eCRF. ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 19:57:10
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	22 Mar 2021 15:56:35

US3362125

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:47
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered '22 Mar 2021'	Alexandra Caillouet (b) (4)	22 Mar 2021 15:56:35

US3362125

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:17:16

[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 08:34:47
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered 'Clinic (Clinic)'	Alexandra Caillouet (b) (4)	22 Mar 2021 15:56:35

US3362125

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:17:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:47
User entered 'VISIT4'	System	22 Mar 2021 15:56:35

US3362125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:47
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
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 17:15:17
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 13:25:15
User entered 'Yes (Y)' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	07 Apr 2021 13:24:58
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 17:42:25
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 17:42:25
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 19:45:07

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Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

[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).	(b) (4), (b) (6)	05 Apr 2021 19:36:42
User entered 'No (N)'	(b) (4), (b) (6)	29 Mar 2021 21:47:25

US3362125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:47
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered '22 Mar 2021' reason for change: Data Entry Error	(b) (4)	07 Apr 2021 13:24:58
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 21:47:25

US3362125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:47
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered '09:55' reason for change: Data Entry Error	(b) (4)	07 Apr 2021 13:24:58
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 21:47:25

US3362125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:47
User entered '22 Mar 2021 09:55'	System	07 Apr 2021 13:24:58
User entered empty.	System	29 Mar 2021 21:47:25

US3362125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:47
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered '36.8' C reason for change: Data Entry Error	(b) (4)	07 Apr 2021 13:24:58
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 21:47:25

US3362125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:47
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	07 Apr 2021 13:24:58
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 21:47:25

US3362125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:47
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:47:25

US3362125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:47
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered '67' reason for change: Data Entry Error	(b) (4)	07 Apr 2021 13:24:58
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 21:47:25

US3362125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:47
User entered 'bpm'	System	07 Apr 2021 13:24:58
User entered empty.	System	29 Mar 2021 21:47:25

US3362125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:47
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered '18' reason for change: Data Entry Error	(b) (4)	07 Apr 2021 13:24:58
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 21:47:25

US3362125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:47
User entered 'breaths/min'	System	07 Apr 2021 13:24:58
User entered empty.	System	29 Mar 2021 21:47:25

US3362125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:47
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered '142' reason for change: Data Entry Error	(b) (4)	07 Apr 2021 13:24:58
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 21:47:25

US3362125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:47
User entered 'mmHg'	System	07 Apr 2021 13:24:58
User entered empty.	System	29 Mar 2021 21:47:25

US3362125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:47
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered '93' reason for change: Data Entry Error	(b) (4)	07 Apr 2021 13:24:58
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 21:47:25

US3362125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:47
User entered 'mmHg'	System	07 Apr 2021 13:24:58
User entered empty.	System	29 Mar 2021 21:47:25

US3362125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:47

US3362125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:47

US3362125

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:17:16

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:47
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User closed query 'Per CDM: Please be aware that Visit 4 and OL-D29 took place exactly the same day. However, "Physical Examination" were done on OL-D29, but on Visit 4 it was not done. Please clarify why there is a difference or update the field. Thank you!' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:57:06
Query 'Per CDM: Please be aware that Visit 4 and OL-D29 took place exactly the same day. However, "Physical Examination" were done on OL-D29, but on Visit 4 it was not done. Please clarify why there is a difference or update the field. Thank you!' answered with 'updated' (Site from DM).	Amy Thomassie (b) (4) (b) (4)	28 Mar 2021 14:48:45
User entered 'Yes (Y)' reason for change: Data Entry Error	Amy Thomassie (b) (4) (b) (4)	28 Mar 2021 14:47:51
User opened query 'Per CDM: Please be aware that Visit 4 and OL-D29 took place exactly the same day. However, "Physical Examination" were done on OL-D29, but on Visit 4 it was not done. Please clarify why there is a difference or update the field. Thank you!' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 17:59:23
User entered 'No (N)'	Alexandra Caillouet (b) (4)	22 Mar 2021 15:56:48

US3362125

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:17:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:47
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered '22 Mar 2021' reason for change: Data Entry Error	(b) (4)	28 Mar 2021 14:47:51
User entered empty.	Amy Thomassie (b) (4)	28 Mar 2021 14:47:51
	(b) (4)	
	Alexandra Caillouet	22 Mar 2021 15:56:48
	(b) (4)	

US3362125

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:17:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:47
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	22 Mar 2021 15:57:04

US3362125

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:17:16

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:47
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered '22 Mar 2021'	Alexandra Caillouet (b) (4)	22 Mar 2021 15:57:04

US3362125

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:17:16

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:47
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered '10:08'	Alexandra Caillouet (b) (4)	22 Mar 2021 15:57:04

US3362125

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:17:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:47
User entered '22 Mar 2021 10:08'	System	22 Mar 2021 15:57:04

US3362125

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:47
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	22 Mar 2021 15:57:10

US3362125

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:47
User entered 'I'	System	22 Mar 2021 15:57:10

US3362125

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 20:34:48

US3362125

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered '13 Apr 2021'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 20:34:48

US3362125

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 20:34:48

US3362125

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 20:34:48

US3362125

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 20:34:52

US3362125

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:16

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Apr 2021 20:34:52

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:17:16

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:16
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:35:26
User entered '9 Nov 2020'	(b) (4), (b) (6)	09 Nov 2020 17:57:32

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:17:16

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:16
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:35:26
User entered '11:05'	(b) (4), (b) (6)	09 Nov 2020 17:57:32

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:17:16

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:16
User entered '9 Nov 2020 11:05'	System	09 Nov 2020 17:57:32

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:17:16

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:16
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:35:26
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	(b) (4), (b) (6)	09 Nov 2020 17:57:32

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:17:16

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:16
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:35:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Nov 2020 17:57:32

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:17:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered 'Day 2 (Day 2)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:53:44
User entered 'Day 1 (Day 1)'	(b) (4), (b) (6)	09 Nov 2020 18:15:56

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:17:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered '9 Nov 2020'	(b) (4), (b) (6)	09 Nov 2020 18:15:56

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:17:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 18:15:56

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:17:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered '95'	(b) (4), (b) (6)	09 Nov 2020 18:15:56

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:17:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User entered '%'	System	09 Nov 2020 18:15:56

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:17:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered '37.0' C	(b) (4), (b) (6)	09 Nov 2020 18:15:56

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:17:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	09 Nov 2020 18:15:56

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:17:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'Mild (Mild)'	(b) (4), (b) (6)	09 Nov 2020 18:15:56

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:17:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	09 Nov 2020 18:15:56

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:17:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	09 Nov 2020 18:15:56

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:17:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'Mild (Mild)'	(b) (4), (b) (6)	09 Nov 2020 18:15:56

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:17:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	09 Nov 2020 18:15:56

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:17:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'Mild (Mild)'	(b) (4), (b) (6)	09 Nov 2020 18:15:56

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:17:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'Mild (Mild)'	(b) (4), (b) (6)	09 Nov 2020 18:15:56

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:17:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	09 Nov 2020 18:15:56

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:17:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	09 Nov 2020 18:15:56

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:17:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	09 Nov 2020 18:15:56

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:17:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	09 Nov 2020 18:15:56

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:17:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	09 Nov 2020 18:15:56

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:17:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	09 Nov 2020 18:15:56

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:17:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	09 Nov 2020 18:15:56

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:17:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'Mild (Mild)'	(b) (4), (b) (6)	09 Nov 2020 18:15:56

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:17:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered 'Day 1 (Day 1)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:54:00

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:17:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered '8 Nov 2020'	(b) (4), (b) (6)	10 Nov 2020 15:54:00

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:17:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 00:29:28
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Un-verified.	(b) (4)	20 Apr 2021 22:32:28
User entered '0' reason for change: Data Entry Error	Alexandra Caillouet	20 Apr 2021 22:32:28
DataPoint Verified.	(b) (4)	19 Nov 2020 18:39:26
User entered '1'	(b) (4), (b) (6)	10 Nov 2020 15:54:00

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:17:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 00:29:28
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Un-verified.	(b) (4)	
	Alexandra Caillouet	20 Apr 2021 22:32:28
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Apr 2021 22:32:28
Query '	(b) (4), (b) (6)	20 Apr 2021 12:57:39
Per CDM: Assessment Not Done is checked, however data is present in Temperature field. Please review and update accordingly, else clarify.		
' canceled (Site from DM).		
User opened query '	(b) (4), (b) (6)	20 Apr 2021 12:57:33
Per CDM: Assessment Not Done is checked, however data is present in Temperature field. Please review and update accordingly, else clarify.		
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 15:54:00

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:17:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User entered '%'	System	20 Apr 2021 22:32:28
User entered empty.	System	10 Nov 2020 15:54:00

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:17:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User closed query ' Per CDM: Assessment Not Done is checked, however data is present in Temperature field. Please review and update accordingly, else clarify' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:11:21
Query ' Per CDM: Assessment Not Done is checked, however data is present in Temperature field. Please review and update accordingly, else clarify' answered with 'update' (Site from DM).	Alexandra Caillouet (b) (4)	20 Apr 2021 22:32:54
User opened query ' Per CDM: Assessment Not Done is checked, however data is present in Temperature field. Please review and update accordingly, else clarify' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 12:57:47
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Nov 2020 15:54:09
User entered '100.9' F reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 15:54:09
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Nov 2020 15:54:00
User entered '100' (non-conformant).	(b) (4), (b) (6)	10 Nov 2020 15:54:00

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:17:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 00:29:28
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Un-verified.	(b) (4)	20 Apr 2021 22:32:28
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Alexandra Caillouet	20 Apr 2021 22:32:28
DataPoint Verified.	(b) (4)	19 Nov 2020 18:39:26
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 15:54:00

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:17:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 00:29:28
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Un-verified.	(b) (4)	20 Apr 2021 22:32:28
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Alexandra Caillouet	20 Apr 2021 22:32:28
DataPoint Verified.	(b) (4)	19 Nov 2020 18:39:26
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 15:54:00

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:17:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 00:29:28
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Un-verified.	(b) (4)	20 Apr 2021 22:32:28
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Alexandra Caillouet	20 Apr 2021 22:32:28
DataPoint Verified.	(b) (4)	19 Nov 2020 18:39:26
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 15:54:00

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:17:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 00:29:28
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Un-verified.	(b) (4)	20 Apr 2021 22:32:28
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Alexandra Caillouet	20 Apr 2021 22:32:28
DataPoint Verified.	(b) (4)	19 Nov 2020 18:39:26
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 15:54:00

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:17:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 00:29:28
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Un-verified.	(b) (4)	20 Apr 2021 22:32:28
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Alexandra Caillouet	20 Apr 2021 22:32:28
DataPoint Verified.	(b) (4)	19 Nov 2020 18:39:26
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 15:54:00

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:17:16

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 00:29:28
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Un-verified.	(b) (4)	20 Apr 2021 22:32:28
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Alexandra Caillouet	20 Apr 2021 22:32:28
DataPoint Verified.	(b) (4)	19 Nov 2020 18:39:26
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 15:54:00

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:17:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 00:29:28
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Un-verified.	(b) (4)	20 Apr 2021 22:32:28
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Alexandra Caillouet	20 Apr 2021 22:32:28
DataPoint Verified.	(b) (4)	19 Nov 2020 18:39:26
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 15:54:00

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:17:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 00:29:28
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Un-verified.	(b) (4)	20 Apr 2021 22:32:28
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Alexandra Caillouet	20 Apr 2021 22:32:28
DataPoint Verified.	(b) (4)	19 Nov 2020 18:39:26
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 15:54:00

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:17:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 00:29:28
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Un-verified.	(b) (4)	20 Apr 2021 22:32:28
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Alexandra Caillouet	20 Apr 2021 22:32:28
DataPoint Verified.	(b) (4)	19 Nov 2020 18:39:26
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 15:54:00

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:17:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 00:29:28
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Un-verified.	(b) (4)	20 Apr 2021 22:32:28
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Alexandra Caillouet	20 Apr 2021 22:32:28
DataPoint Verified.	(b) (4)	19 Nov 2020 18:39:26
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 15:54:00

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:17:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 00:29:28
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Un-verified.	(b) (4)	20 Apr 2021 22:32:28
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Alexandra Caillouet	20 Apr 2021 22:32:28
DataPoint Verified.	(b) (4)	19 Nov 2020 18:39:26
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 15:54:00

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:17:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 00:29:28
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Un-verified.	(b) (4)	20 Apr 2021 22:32:28
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Alexandra Caillouet	20 Apr 2021 22:32:28
DataPoint Verified.	(b) (4)	19 Nov 2020 18:39:26
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 15:54:00

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:17:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 00:29:28
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Un-verified.	(b) (4)	20 Apr 2021 22:32:28
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Alexandra Caillouet	20 Apr 2021 22:32:28
DataPoint Verified.	(b) (4)	19 Nov 2020 18:39:26
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 15:54:00

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:17:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 00:29:28
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Un-verified.	(b) (4)	20 Apr 2021 22:32:28
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Alexandra Caillouet	20 Apr 2021 22:32:28
DataPoint Verified.	(b) (4)	19 Nov 2020 18:39:26
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 15:54:00

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:17:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 00:29:28
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Un-verified.	(b) (4)	20 Apr 2021 22:32:28
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Alexandra Caillouet	20 Apr 2021 22:32:28
DataPoint Verified.	(b) (4)	19 Nov 2020 18:39:26
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 15:54:00

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:17:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 00:29:28
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Un-verified.	(b) (4)	20 Apr 2021 22:32:28
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Alexandra Caillouet	20 Apr 2021 22:32:28
DataPoint Verified.	(b) (4)	19 Nov 2020 18:39:26
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 15:54:00

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:17:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered 'Day 3 (Day 3)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:55:16

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:17:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered '10 Nov 2020'	(b) (4), (b) (6)	10 Nov 2020 15:55:16

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:17:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 15:55:16

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:17:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered '95'	(b) (4), (b) (6)	10 Nov 2020 15:55:16

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:17:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User entered '%'	System	10 Nov 2020 15:55:16

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:17:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered '97.9' F	(b) (4), (b) (6)	10 Nov 2020 15:55:16

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:17:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	10 Nov 2020 15:55:16

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:17:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'Mild (Mild)'	(b) (4), (b) (6)	10 Nov 2020 15:55:16

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:17:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	10 Nov 2020 15:55:16

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:17:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	10 Nov 2020 15:55:16

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:17:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	10 Nov 2020 15:55:16

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:17:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'Mild (Mild)'	(b) (4), (b) (6)	10 Nov 2020 15:55:16

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:17:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'Mild (Mild)'	(b) (4), (b) (6)	10 Nov 2020 15:55:16

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:17:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	10 Nov 2020 15:55:16

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:17:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	10 Nov 2020 15:55:16

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:17:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	10 Nov 2020 15:55:16

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:17:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	10 Nov 2020 15:55:16

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:17:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	10 Nov 2020 15:55:16

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:17:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	10 Nov 2020 15:55:16

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:17:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	10 Nov 2020 15:55:16

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:17:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	10 Nov 2020 15:55:16

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:17:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	10 Nov 2020 15:55:16

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:17:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered 'Day 4 (Day 4)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:34:10

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:17:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered '11 Nov 2020'	(b) (4), (b) (6)	11 Nov 2020 17:34:10

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:17:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 17:34:10

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:17:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered '94'	(b) (4), (b) (6)	11 Nov 2020 17:34:10

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:17:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User entered '%'	System	11 Nov 2020 17:34:10

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:17:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered '96.8' F	(b) (4), (b) (6)	11 Nov 2020 17:34:10

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:17:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	11 Nov 2020 17:34:10

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:17:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	11 Nov 2020 17:34:10

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:17:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	11 Nov 2020 17:34:10

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:17:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	11 Nov 2020 17:34:10

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:17:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'Mild (Mild)'	(b) (4), (b) (6)	11 Nov 2020 17:34:10

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:17:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	11 Nov 2020 17:34:10

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:17:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	11 Nov 2020 17:34:10

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:17:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	11 Nov 2020 17:34:10

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:17:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	11 Nov 2020 17:34:10

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:17:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	11 Nov 2020 17:34:10

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:17:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	11 Nov 2020 17:34:10

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:17:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	11 Nov 2020 17:34:10

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:17:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	11 Nov 2020 17:34:10

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:17:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	11 Nov 2020 17:34:10

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:17:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	11 Nov 2020 17:34:10

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:17:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	11 Nov 2020 17:34:10

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:17:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered 'Day 5 (Day 5)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:00:57

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:17:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered '12 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 18:00:57

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:17:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered '0'	(b) (4), (b) (6)	12 Nov 2020 18:00:57

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:17:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered '95'	(b) (4), (b) (6)	12 Nov 2020 18:00:57

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:17:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User entered '%'	System	12 Nov 2020 18:00:57

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:17:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered '96.5' F	(b) (4), (b) (6)	12 Nov 2020 18:00:57

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:17:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 18:00:57

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:17:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 18:00:57

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:17:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 18:00:57

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:17:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 18:00:57

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:17:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 18:00:57

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:17:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 18:00:57

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:17:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 18:00:57

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:17:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 18:00:57

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:17:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 18:00:57

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:17:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 18:00:57

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:17:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 18:00:57

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:17:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 18:00:57

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:17:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 18:00:57

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:17:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 18:00:57

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:17:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 18:00:57

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:17:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 18:00:57

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:17:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered 'Day 6 (Day 6)'	Crystal Rowell (b) (4)	13 Nov 2020 18:11:14

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:17:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered '13 Nov 2020'	Crystal Rowell (b) (4)	13 Nov 2020 18:11:14
	(b) (4)	

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:17:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered '0'	Crystal Rowell (b) (4)	13 Nov 2020 18:11:14

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:17:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered '98'	Crystal Rowell (b) (4)	13 Nov 2020 18:11:14

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:17:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User entered '%'	System	13 Nov 2020 18:11:14

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:17:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered '96.5' F	Crystal Rowell (b) (4)	13 Nov 2020 18:11:14

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:17:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	Crystal Rowell (b) (4)	13 Nov 2020 18:11:14
	(b) (4)	

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:17:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	Crystal Rowell (b) (4)	13 Nov 2020 18:11:14

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:17:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	Crystal Rowell (b) (4)	13 Nov 2020 18:11:14

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:17:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	Crystal Rowell (b) (4)	13 Nov 2020 18:11:14

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:17:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	Crystal Rowell (b) (4)	13 Nov 2020 18:11:14
	(b) (4)	

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:17:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	Crystal Rowell (b) (4)	13 Nov 2020 18:11:14
	(b) (4)	

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:17:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	Crystal Rowell (b) (4)	13 Nov 2020 18:11:14

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:17:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	Crystal Rowell (b) (4)	13 Nov 2020 18:11:14

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:17:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	Crystal Rowell (b) (4)	13 Nov 2020 18:11:14

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:17:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	Crystal Rowell (b) (4)	13 Nov 2020 18:11:14

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:17:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	Crystal Rowell (b) (4)	13 Nov 2020 18:11:14

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:17:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	Crystal Rowell (b) (4)	13 Nov 2020 18:11:14
	(b) (4)	

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:17:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	Crystal Rowell (b) (4)	13 Nov 2020 18:11:14
	(b) (4)	

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:17:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	Crystal Rowell (b) (4)	13 Nov 2020 18:11:14
	(b) (4)	

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:17:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	Crystal Rowell (b) (4)	13 Nov 2020 18:11:14

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:17:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	Crystal Rowell (b) (4)	13 Nov 2020 18:11:14

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:17:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered 'Day 7 (Day 7)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:01:37

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:17:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered '14 Nov 2020'	(b) (4), (b) (6)	16 Nov 2020 21:01:37

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:17:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 21:01:37

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:17:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered '96'	(b) (4), (b) (6)	16 Nov 2020 21:01:37

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:17:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User entered '%'	System	16 Nov 2020 21:01:37

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:17:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered '98' F	(b) (4), (b) (6)	16 Nov 2020 21:01:37

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:17:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:01:37

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:17:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:01:37

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:17:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:01:37

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:17:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:01:37

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:17:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:01:37

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:17:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:01:37

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:17:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:01:37

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:17:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:01:37

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:17:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:01:37

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:17:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:01:37

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:17:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:01:37

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:17:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:01:37

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:17:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:01:37

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:17:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:01:37

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:17:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:01:37

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:17:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:01:37

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:17:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered 'Day 8 (Day 8)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:02:28

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:17:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered '15 Nov 2020'	(b) (4), (b) (6)	16 Nov 2020 21:02:28

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:17:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 21:02:28

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:17:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered '95'	(b) (4), (b) (6)	16 Nov 2020 21:02:28

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:17:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User entered '%'	System	16 Nov 2020 21:02:28

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:17:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered '97' F	(b) (4), (b) (6)	16 Nov 2020 21:02:28

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:17:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:02:28

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:17:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:02:28

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:17:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:02:28

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:17:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:02:28

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:17:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:02:28

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:17:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:02:28

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:17:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:02:28

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:17:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:02:28

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:17:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:02:28

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:17:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:02:28

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:17:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:02:28

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:17:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:02:28

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:17:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:02:28

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:17:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:02:28

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:17:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:02:28

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:17:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:02:28

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:17:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered 'Day 9 (Day 9)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:10:18

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:17:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered '16 Nov 2020'	(b) (4), (b) (6)	16 Nov 2020 21:10:18

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:17:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 21:10:18

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:17:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered '97'	(b) (4), (b) (6)	16 Nov 2020 21:10:18

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:17:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User entered '%'	System	16 Nov 2020 21:10:18

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:17:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered '97' F	(b) (4), (b) (6)	16 Nov 2020 21:10:18

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:17:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:10:18

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:17:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:10:18

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:17:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:10:18

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:17:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:10:18

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:17:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:10:18

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:17:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:10:18

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:17:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:10:18

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:17:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:10:18

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:17:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:10:18

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:17:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:10:18

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:17:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:10:18

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:17:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:10:18

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:17:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:10:18

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:17:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:10:18

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:17:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:10:18

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:17:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:10:18

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:17:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered 'Day 10 (Day 10)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:33:54

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:17:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered '17 Nov 2020'	(b) (4), (b) (6)	17 Nov 2020 15:33:54

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:17:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 15:33:54

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:17:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered '97'	(b) (4), (b) (6)	17 Nov 2020 15:33:54

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:17:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User entered '%'	System	17 Nov 2020 15:33:54

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:17:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered '96.2' F	(b) (4), (b) (6)	17 Nov 2020 15:33:54

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:17:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 15:33:54

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:17:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 15:33:54

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:17:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 15:33:54

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:17:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 15:33:54

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:17:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 15:33:54

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:17:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 15:33:54

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:17:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 15:33:54

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:17:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 15:33:54

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:17:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 15:33:54

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:17:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 15:33:54

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:17:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 15:33:54

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:17:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 15:33:54

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:17:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 15:33:54

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:17:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 15:33:54

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:17:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 15:33:54

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:17:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 15:33:54

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:17:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered 'Day 11 (Day 11)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:58:09

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:17:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered '18 Nov 2020'	(b) (4), (b) (6)	18 Nov 2020 18:58:09

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:17:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered '0'	(b) (4), (b) (6)	18 Nov 2020 18:58:09

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:17:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered '95'	(b) (4), (b) (6)	18 Nov 2020 18:58:09

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:17:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User entered '%'	System	18 Nov 2020 18:58:09

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:17:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered '96.9' F	(b) (4), (b) (6)	18 Nov 2020 18:58:09

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:17:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 18:58:09

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:17:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 18:58:09

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:17:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 18:58:09

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:17:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 18:58:09

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:17:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 18:58:09

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:17:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 18:58:09

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:17:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 18:58:09

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:17:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 18:58:09

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:17:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 18:58:09

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:17:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 18:58:09

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:17:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 18:58:09

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:17:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 18:58:09

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:17:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 18:58:09

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:17:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 18:58:09

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:17:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 18:58:09

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:17:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 18:58:09

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:17:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered 'Day 12 (Day 12)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:10:06

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:17:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered '19 Nov 2020'	(b) (4), (b) (6)	19 Nov 2020 16:10:06

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:17:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 16:10:06

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:17:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered '97'	(b) (4), (b) (6)	19 Nov 2020 16:10:06

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:17:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User entered '%'	System	19 Nov 2020 16:10:06

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:17:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered '97.2' F	(b) (4), (b) (6)	19 Nov 2020 16:10:06

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:17:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 16:10:06

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:17:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 16:10:06

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:17:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 16:10:06

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:17:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 16:10:06

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:17:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 16:10:06

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:17:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 16:10:06

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:17:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 16:10:06

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:17:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 16:10:06

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:17:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 16:10:06

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:17:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 16:10:06

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:17:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 16:10:06

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:17:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 16:10:06

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:17:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 16:10:06

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:17:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 16:10:06

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:17:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 16:10:06

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:17:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:26
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 16:10:06

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:17:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered 'Day 13 (Day 13)'	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:30:43

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:17:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	24 Nov 2020 22:19:49
User entered '20 Nov 2020'	(b) (4), (b) (6)	20 Nov 2020 21:30:43

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:17:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:19:49
User entered '0'	(b) (4), (b) (6)	20 Nov 2020 21:30:43

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:17:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	24 Nov 2020 22:19:49
User entered '97'	(b) (4), (b) (6)	20 Nov 2020 21:30:43

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:17:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User entered '%'	System	20 Nov 2020 21:30:43

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:17:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	24 Nov 2020 22:19:49
User entered '96.8' F	(b) (4), (b) (6)	20 Nov 2020 21:30:43

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:17:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	24 Nov 2020 22:19:49
User entered 'None (None)'	(b) (4), (b) (6)	20 Nov 2020 21:30:43

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:17:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	24 Nov 2020 22:19:49
User entered 'None (None)'	(b) (4), (b) (6)	20 Nov 2020 21:30:43

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:17:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	24 Nov 2020 22:19:49
User entered 'None (None)'	(b) (4), (b) (6)	20 Nov 2020 21:30:43

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:17:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	24 Nov 2020 22:19:49
User entered 'None (None)'	(b) (4), (b) (6)	20 Nov 2020 21:30:43

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:17:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	24 Nov 2020 22:19:49
User entered 'None (None)'	(b) (4), (b) (6)	20 Nov 2020 21:30:43

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:17:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	24 Nov 2020 22:19:49
User entered 'None (None)'	(b) (4), (b) (6)	20 Nov 2020 21:30:43

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:17:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	24 Nov 2020 22:19:49
User entered 'None (None)'	(b) (4), (b) (6)	20 Nov 2020 21:30:43

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:17:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:19:49
User entered 'None (None)'	(b) (4), (b) (6)	20 Nov 2020 21:30:43

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:17:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:19:49
User entered 'None (None)'	(b) (4), (b) (6)	20 Nov 2020 21:30:43

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:17:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:19:49
User entered 'None (None)'	(b) (4), (b) (6)	20 Nov 2020 21:30:43

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:17:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	24 Nov 2020 22:19:49
User entered 'None (None)'	(b) (4), (b) (6)	20 Nov 2020 21:30:43

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:17:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	24 Nov 2020 22:19:49
User entered 'None (None)'	(b) (4), (b) (6)	20 Nov 2020 21:30:43

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:17:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	24 Nov 2020 22:19:49
User entered 'None (None)'	(b) (4), (b) (6)	20 Nov 2020 21:30:43

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:17:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	24 Nov 2020 22:19:49
User entered 'None (None)'	(b) (4), (b) (6)	20 Nov 2020 21:30:43

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:17:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	24 Nov 2020 22:19:49
User entered 'None (None)'	(b) (4), (b) (6)	20 Nov 2020 21:30:43

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:17:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:19:49
User entered 'None (None)'	(b) (4), (b) (6)	20 Nov 2020 21:30:43

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:17:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered 'Day 14 (Day 14)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:31:08

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:17:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	24 Nov 2020 22:19:49
User entered '21 Nov 2020'	(b) (4), (b) (6)	23 Nov 2020 18:31:08

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:17:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:19:49
User entered '0'	(b) (4), (b) (6)	23 Nov 2020 18:31:08

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:17:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	24 Nov 2020 22:19:49
User entered '94'	(b) (4), (b) (6)	23 Nov 2020 18:31:08

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:17:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User entered '%'	System	23 Nov 2020 18:31:08

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:17:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	24 Nov 2020 22:19:49
User entered '96.9' F	(b) (4), (b) (6)	23 Nov 2020 18:31:08

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:17:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	24 Nov 2020 22:19:49
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 18:31:08

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:17:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 22:19:49
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 18:31:08

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:17:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	24 Nov 2020 22:19:49
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 18:31:08

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:17:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	24 Nov 2020 22:19:49
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 18:31:08

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:17:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	24 Nov 2020 22:19:49
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 18:31:08

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:17:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	24 Nov 2020 22:19:49
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 18:31:08

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:17:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	24 Nov 2020 22:19:49
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 18:31:08

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:17:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	24 Nov 2020 22:19:49
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 18:31:08

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:17:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	24 Nov 2020 22:19:49
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 18:31:08

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:17:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:19:49
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 18:31:08

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:17:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	24 Nov 2020 22:19:49
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 18:31:08

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:17:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	24 Nov 2020 22:19:49
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 18:31:08

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:17:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	24 Nov 2020 22:19:49
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 18:31:08

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:17:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	24 Nov 2020 22:19:49
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 18:31:08

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:17:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	24 Nov 2020 22:19:49
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 18:31:08

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:17:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	24 Nov 2020 22:19:49
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 18:31:08

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:17:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered 'Day 15 (Day 15)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:31:58

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:17:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	24 Nov 2020 22:19:49
User entered '22 Nov 2020'	(b) (4), (b) (6)	23 Nov 2020 18:31:58

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:17:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:19:49
User entered '0'	(b) (4), (b) (6)	23 Nov 2020 18:31:58

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:17:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	24 Nov 2020 22:19:49
User entered '97'	(b) (4), (b) (6)	23 Nov 2020 18:31:58

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:17:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User entered '%'	System	23 Nov 2020 18:31:58

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:17:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	24 Nov 2020 22:19:49
User entered '97.1' F	(b) (4), (b) (6)	23 Nov 2020 18:31:58

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:17:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	24 Nov 2020 22:19:49
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 18:31:58

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:17:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	24 Nov 2020 22:19:49
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 18:31:58

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:17:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	24 Nov 2020 22:19:49
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 18:31:58

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:17:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	24 Nov 2020 22:19:49
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 18:31:58

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:17:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	24 Nov 2020 22:19:49
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 18:31:58

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:17:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	24 Nov 2020 22:19:49
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 18:31:58

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:17:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	24 Nov 2020 22:19:49
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 18:31:58

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:17:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	24 Nov 2020 22:19:49
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 18:31:58

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:17:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	24 Nov 2020 22:19:49
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 18:31:58

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:17:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:19:49
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 18:31:58

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:17:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	24 Nov 2020 22:19:49
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 18:31:58

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:17:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	24 Nov 2020 22:19:49
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 18:31:58

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:17:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	24 Nov 2020 22:19:49
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 18:31:58

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:17:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	24 Nov 2020 22:19:49
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 18:31:58

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:17:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	24 Nov 2020 22:19:49
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 18:31:58

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:17:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:22
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	24 Nov 2020 22:19:49
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 18:31:58

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:17:16

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:26
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:43:17
User entered '9 Nov 2020'	(b) (4), (b) (6)	10 Nov 2020 15:52:55

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:17:16

[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 07:50:26
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:43:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 15:52:55

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:17:16

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 07:50:26
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:43:17
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)	19 Nov 2020 15:00:17
User closed query 'Per CDM: Please consider to update results when available and keep this query open until results are updated here. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 15:00:03
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 'updated' (Site from System).	Crystal Rowell (b) (4) (b) (4)	13 Nov 2020 16:35:42
Query 'Per CDM: Please consider to update results when available and keep this query open until results are updated here. Thank you.' answered with 'updated, results were positive' (Site from DM).	Crystal Rowell (b) (4) (b) (4)	13 Nov 2020 16:35:38
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	13 Nov 2020 16:35:18
User entered 'Yes (Y)' reason for change: Data Entry Error	Crystal Rowell (b) (4) (b) (4)	13 Nov 2020 16:35:18
User opened query 'Per CDM: Please consider to update results when available and keep this query open until results are updated here. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 06:12:52
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 06:11:24
Query 'Data is required. Please complete.' answered with 'pending ' (Site from System).	(b) (4), (b) (6)	10 Nov 2020 15:53:03
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 15:52:55
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 15:52:55

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[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:26
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:43:17
User entered '9 Nov 2020'	(b) (4), (b) (6)	10 Nov 2020 15:52:55

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[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:26
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:43:17
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4), (b) (6)	10 Nov 2020 15:52:55

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Form: COVID Diagnostic Test

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[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:26
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:43:17
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 15:52:55

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[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:26
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:43:17
User entered 'No (N)'	(b) (4), (b) (6)	10 Nov 2020 15:52:55

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[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:26
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:43:17
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 15:52:55

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[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:26
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:43:17
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 15:52:55

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[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:26
User entered 'I'	System	13 Nov 2020 16:35:18

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Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:31
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:46:09
User entered 'No (N)'	Crystal Rowell (b) (4)	13 Nov 2020 17:09:43

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Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:31
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:46:09
User entered empty.	Crystal Rowell (b) (4)	13 Nov 2020 17:09:43

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Folder: Covid-19 Assessment 09 Nov 2020

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:31
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:46:09
User entered empty.	Crystal Rowell (b) (4)	13 Nov 2020 17:09:43

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[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:31
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	19 Nov 2020 18:46:09
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 17:09:43
	Crystal Rowell (b) (4)	
	(b) (4)	

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Did the subject have Heart Rate \geq 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:31
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:46:09
User entered 'No (N)'	Crystal Rowell (b) (4)	13 Nov 2020 17:09:43

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Generated On: 09 Jun 2021 17:17:16

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:31
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:46:09
User entered empty.	Crystal Rowell (b) (4)	13 Nov 2020 17:09:43

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Folder: Covid-19 Assessment 09 Nov 2020

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Generated On: 09 Jun 2021 17:17:16

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:31
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:46:09
User entered empty.	Crystal Rowell (b) (4)	13 Nov 2020 17:09:43

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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:31
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:46:09
User entered empty.	Crystal Rowell (b) (4)	13 Nov 2020 17:09:43

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Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:31
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:46:09
User entered 'No (N)'	Crystal Rowell (b) (4)	13 Nov 2020 17:09:43

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:31
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:46:09
User entered empty.	Crystal Rowell (b) (4)	13 Nov 2020 17:09:43

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:31
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:46:09
User entered empty.	Crystal Rowell (b) (4)	13 Nov 2020 17:09:43

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:31
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:46:09
User entered empty.	Crystal Rowell (b) (4)	13 Nov 2020 17:09:43

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Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:31
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:46:09
User entered 'No (N)'	Crystal Rowell (b) (4)	13 Nov 2020 17:09:43

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:31
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:46:09
User entered empty.	Crystal Rowell (b) (4)	13 Nov 2020 17:09:43

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Folder: Covid-19 Assessment 09 Nov 2020

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:31
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:46:09
User entered empty.	Crystal Rowell (b) (4)	13 Nov 2020 17:09:43

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:31
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:46:09
User entered empty.	Crystal Rowell (b) (4)	13 Nov 2020 17:09:43

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[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:31
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:46:09
User entered 'No (N)'	Crystal Rowell (b) (4)	13 Nov 2020 17:09:43

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Folder: Covid-19 Assessment 09 Nov 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:31
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:46:09
User entered empty.	Crystal Rowell (b) (4)	13 Nov 2020 17:09:43

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Folder: Covid-19 Assessment 09 Nov 2020

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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:31
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:46:09
User entered 'No (N)'	Crystal Rowell (b) (4)	13 Nov 2020 17:09:43

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:31
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:46:09
User entered empty.	Crystal Rowell (b) (4)	13 Nov 2020 17:09:43

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:31
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:46:09
User entered 'No (N)'	Crystal Rowell (b) (4)	13 Nov 2020 17:09:43

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:31
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:46:09
User entered empty.	Crystal Rowell (b) (4)	13 Nov 2020 17:09:43

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:31
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:46:09
User entered empty.	Crystal Rowell (b) (4)	13 Nov 2020 17:09:43

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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:31
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:46:09
User entered 'No (N)'	Crystal Rowell (b) (4)	13 Nov 2020 17:09:43

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:31
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:46:09
User entered empty.	Crystal Rowell (b) (4)	13 Nov 2020 17:09:43

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:31
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:46:09
User entered empty.	Crystal Rowell (b) (4)	13 Nov 2020 17:09:43

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[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:31
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:46:09
User entered 'No (N)'	Crystal Rowell (b) (4)	13 Nov 2020 17:09:43

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:31
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:46:09
User entered empty.	Crystal Rowell (b) (4)	13 Nov 2020 17:09:43

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:31
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:46:09
User entered empty.	Crystal Rowell (b) (4)	13 Nov 2020 17:09:43

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[ECMO?](#)

Audit	User	Time (GMT)
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User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:46:09
User entered 'No (N)'	Crystal Rowell (b) (4)	13 Nov 2020 17:09:43

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DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:46:09
User entered empty.	Crystal Rowell (b) (4)	13 Nov 2020 17:09:43

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:31
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:46:09
User entered empty.	Crystal Rowell (b) (4)	13 Nov 2020 17:09:43

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

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Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:31
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:46:09
User entered 'No (N)'	Crystal Rowell (b) (4)	13 Nov 2020 17:09:43

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:31
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:46:09
User entered empty.	Crystal Rowell (b) (4)	13 Nov 2020 17:09:43

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:31
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:46:09
User entered empty.	Crystal Rowell (b) (4)	13 Nov 2020 17:09:43

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[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:31
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:46:09
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Folder: Covid-19 Assessment 09 Nov 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:31
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:46:09
User entered empty.	Crystal Rowell (b) (4)	13 Nov 2020 17:09:43

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:17:16

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:31
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:46:09
User entered empty.	Crystal Rowell (b) (4)	13 Nov 2020 17:09:43

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:17:16

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:31
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:46:09
User entered 'No (N)'	Crystal Rowell (b) (4)	13 Nov 2020 17:09:43

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:17:16

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:31
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:46:09
User entered empty.	Crystal Rowell (b) (4)	13 Nov 2020 17:09:43

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

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[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:31
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:46:09
User entered 'No (N)'	Crystal Rowell (b) (4)	13 Nov 2020 17:09:43

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:17:16

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:31
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:46:09
User entered empty.	Crystal Rowell (b) (4)	13 Nov 2020 17:09:43

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:17:16

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:31
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:46:09
User entered 'No (N)'	Crystal Rowell (b) (4)	13 Nov 2020 17:09:43

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:17:16

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:31
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:46:09
User entered empty.	Crystal Rowell (b) (4)	13 Nov 2020 17:09:43

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:17:16

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:31
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:46:09
User entered 'No (N)'	Crystal Rowell (b) (4)	13 Nov 2020 17:09:43

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:17:16

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:31
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:46:09
User entered empty.	Crystal Rowell (b) (4)	13 Nov 2020 17:09:43

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:17:16

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:31
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:46:09
User entered 'No (N)'	Crystal Rowell (b) (4)	13 Nov 2020 17:09:43

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:17:16

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:31
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:46:09
User entered empty.	Crystal Rowell (b) (4)	13 Nov 2020 17:09:43

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:17:16

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:31
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:46:09
User entered 'No (N)'	Crystal Rowell (b) (4)	13 Nov 2020 17:09:43

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:17:16

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:31
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:46:09
User entered empty.	Crystal Rowell (b) (4)	13 Nov 2020 17:09:43

US3362125

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:17:16

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:31
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:46:09
User entered empty.	Crystal Rowell (b) (4)	13 Nov 2020 17:09:43

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:17:16

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:50:35
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:52:02
User entered 'No (N)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	13 Nov 2020 18:23:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	10 Nov 2020 08:21:55
Query 'Data is required. Please complete.' answered with 'entered in error ' (Site from System).	(b) (4), (b) (6)	09 Nov 2020 18:09:20
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 18:09:11
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 18:09:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Nov 2020 18:09:06

US3362125

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:17:16

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:47
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	12 Nov 2020 18:01:22

US3362125

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:17:16

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:47
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:54:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 18:01:22

US3362125

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:17:16

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:47
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	19 Nov 2020 18:54:18
User entered '11 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 18:01:22

US3362125

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:17:16

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:47
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 13NOV2020 is recorded under Illness Visit Day 5 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 06:22:01
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 13NOV2020 is recorded under Illness Visit Day 5 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'Accession Number: 1F67709 ' (Site from DM).	Alexandra Caillouet (b) (4)	08 Dec 2020 17:37:20
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 13NOV2020 is recorded under Illness Visit Day 5 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 06:05:49
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	12 Nov 2020 18:01:22

US3362125

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:17:16

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:47
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	19 Nov 2020 18:54:27
User entered 'Yes (Y)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	13 Nov 2020 18:34:11
Query 'Per CDM: Please consider to update results when available and keep this query open until results get updated here.' canceled (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 08:54:33
User opened query 'Per CDM: Please consider to update results when available and keep this query open until results get updated here.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 08:52:52
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	13 Nov 2020 08:51:30
Query 'Data is required. Please complete.' answered with 'pending' (Site from System).	(b) (4), (b) (6)	12 Nov 2020 18:01:55
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 18:01:22
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 18:01:22

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:17:16

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:47
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15,17NOV2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 11:18:45
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15,17NOV2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'updated' (Site from DM).	Amy Thomassie (b) (4) (b) (4)	28 Nov 2020 13:16:43
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15,17NOV2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 06:43:04
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15NOV2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.	(b) (4), (b) (6)	26 Nov 2020 06:42:50
' canceled (Site from DM).		
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15NOV2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.	(b) (4), (b) (6)	26 Nov 2020 06:42:08
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:54:25

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:17:16

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '13 Nov 2020' reason for change: Data Entry Error	Crystal Rowell (b) (4)	13 Nov 2020 18:34:11
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 18:01:22

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:17:16

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:47
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	12 Nov 2020 18:01:22

US3362125

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:17:16

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:47
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:20:56
User closed query 'Per ETRTR: Please confirm if Saliva was collected after Day 5 and update as applicable.' (Site from CRA).	(b) (4), (b) (6)	17 Jan 2021 19:44:49
Query 'Per ETRTR: Please confirm if Saliva was collected after Day 5 and update as applicable.' answered with 'updated' (Site from CRA).	Amy Thomassie (b) (4) (b) (4)	28 Nov 2020 13:16:30
User entered 'Yes (Y)' reason for change: Data Entry Error	Amy Thomassie (b) (4) (b) (4)	28 Nov 2020 13:16:16
User opened query 'Per ETRTR: Please confirm if Saliva was collected after Day 5 and update as applicable.' (Site from CRA).	(b) (4), (b) (6)	26 Nov 2020 16:00:17
Query 'Per ETRTR: Please confirm if Saliva was collected after Day 3 and update as applicable.' canceled (Site from CRA).		26 Nov 2020 16:00:02
User opened query 'Per ETRTR: Please confirm if Saliva was collected after Day 3 and update as applicable.' (Site from CRA).		26 Nov 2020 15:58:36
User closed query 'Data is required. Please complete.' (Site from System).		13 Nov 2020 08:53:02
Query 'Data is required. Please complete.' answered with 'pending' (Site from System).		12 Nov 2020 18:02:07
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 18:01:22
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 18:01:22

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:17:16

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:47
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	12 Apr 2021 19:20:56
User entered '15 Nov 2020' reason for change: Data Entry Error	Amy Thomassie (b) (4)	28 Nov 2020 13:16:16
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 18:01:22

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:17:16

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:47
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 24,30NOV2020 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)	28 Dec 2020 08:12:39
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 24,30NOV2020 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 'Updated Log' (Site from DM).	Alexandra Caillouet (b) (4)	24 Dec 2020 15:36:22
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 24,30NOV2020 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)	24 Dec 2020 09:23:04
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	12 Nov 2020 18:01:22

US3362125

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:17:16

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:47
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	12 Apr 2021 19:20:56
User entered 'Yes (Y)' reason for change: Data Entry Error	Amy Thomassie (b) (4)	28 Nov 2020 13:16:16
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	13 Nov 2020 08:54:00
Query 'Data is required. Please complete.' answered with 'pending' (Site from System).	(b) (4), (b) (6)	12 Nov 2020 18:02:13
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 18:01:22
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 18:01:22

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:17:16

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:47
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:20:56
User closed query 'Per GCL Lab Reconciliation: Saliva: Requery 1: Please confirm if Saliva sample dated 24NOV2020 was collected for anywhere between day 14 to 28? if yes please update accordingly.Thanks' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 06:39:32
Query 'Per GCL Lab Reconciliation: Saliva: Requery 1: Please confirm if Saliva sample dated 24NOV2020 was collected for anywhere between day 14 to 28? if yes please update accordingly.Thanks' answered with 'Will update. Accession Number: 1F67709' (Site from DM).	Alexandra Caillouet (b) (4)	09 Dec 2020 22:16:38
User opened query 'Per GCL Lab Reconciliation: Saliva: Requery 1: Please confirm if Saliva sample dated 24NOV2020 was collected for anywhere between day 14 to 28? if yes please update accordingly.Thanks' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 07:55:29
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 24NOV2020 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)	09 Dec 2020 07:55:29
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 24NOV2020 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 conducted on 11Nov2020, day 9 saliva sample collected on 17nov2020' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 21:25:07
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 24NOV2020 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)	02 Dec 2020 06:43:04

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EAB) (1725)

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:17:16

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '17 Nov 2020' reason for change: Data Entry Error	Amy Thomassie (b) (4)	28 Nov 2020 13:16:16
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 18:01:22

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:17:16

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:47
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	12 Nov 2020 18:01:22

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:17:16

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:47
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	12 Apr 2021 19:20:56
User entered 'Yes (Y)' reason for change: Data Entry Error	Alexandra Caillouet	09 Dec 2020 22:15:17
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	13 Nov 2020 08:54:06
Query 'Data is required. Please complete.' answered with 'pending' (Site from System).	(b) (4), (b) (6)	12 Nov 2020 18:02:18
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 18:01:22
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 18:01:22

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:17:16

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:47
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:20:56
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 22-NOV-2020 is recorded under Illness visit 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)	28 Dec 2020 08:12:44
User entered '24 Nov 2020' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	24 Dec 2020 15:36:05
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 22-NOV-2020 is recorded under Illness visit 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: 1F67709' (Site from DM).	Alexandra Caillouet (b) (4)	24 Dec 2020 15:33:38
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 22-NOV-2020 is recorded under Illness visit 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)	24 Dec 2020 09:09:41
User entered '22 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Dec 2020 16:57:50
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30NOV2020 is recorded under Illness Visits in PPD, however the sample is missing in EDC. Please review and update as appropriate, else clarify.Thanks' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 06:39:56

US3362125

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:17:16

[Date of Collection](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30NOV2020 is recorded under Illness Visits in PPD, however the sample is missing in EDC. Please review and update as appropriate, else clarify.Thanks' answered with 'Saliva day 21 added with collection date of 30 Nov 2020.' (Site from DM).	Alexandra Caillouet (b) (4)	10 Dec 2020 21:27:22
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30NOV2020 is recorded under Illness Visits in PPD, however the sample is missing in EDC. Please review and update as appropriate, else clarify.Thanks' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 08:37:39
User entered '24 Nov 2020' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	09 Dec 2020 22:15:17
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 18:01:22

US3362125

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:17:16

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:47
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30NOV2020 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)	19 Jan 2021 07:49:40
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30NOV2020 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 'updated' (Site from DM).	Amy Thomassie (b) (4) (b) (4)	08 Jan 2021 22:32:02
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30NOV2020 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)	08 Jan 2021 04:10:11
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 29-NOV-2020 is under Illness visit 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)	29 Dec 2020 06:31:57
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 29-NOV-2020 is under Illness visit 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 'day 21 saliva collected on 01Dec2020, shipped on 14Dec2020. Accession number: 1F67709' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 16:36:39

US3362125

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:17:16

[Visit](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 29-NOV-2020 is under Illness visit 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)	28 Dec 2020 06:42:40
User closed query 'Per GCL Lab Reconciliation Nasopharyngeal Swab1: Sample dated 29-NOV-2020 is under Illness visit 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)	28 Dec 2020 06:42:22
Query 'Per GCL Lab Reconciliation Nasopharyngeal Swab1: Sample dated 29-NOV-2020 is under Illness visit 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 'Nasopharyngeal swab was done during illness visit on 09 Nov 2020 Accession Number: 1F67709. On 30 NOV 2020 Day 21 saliva was collected. ' (Site from DM).	Alexandra Caillouet (b) (4)	24 Dec 2020 15:32:57
User opened query 'Per GCL Lab Reconciliation Nasopharyngeal Swab1: Sample dated 29-NOV-2020 is under Illness visit 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)	24 Dec 2020 09:18:54
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	12 Nov 2020 18:01:22

US3362125

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:17:16

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:47
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	12 Apr 2021 19:20:56
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Dec 2020 21:26:51
User closed query 'Data is required. Please complete.' (Site from System).	Alexandra Caillouet	13 Nov 2020 08:54:12
Query 'Data is required. Please complete.' answered with 'pending' (Site from System).	(b) (4)	12 Nov 2020 18:02:23
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	12 Nov 2020 18:01:22
User entered empty.	System	12 Nov 2020 18:01:22
	(b) (4), (b) (6)	12 Nov 2020 18:01:22

US3362125

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:17:16

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:47
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:20:56
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample recorded under Illness Visit Day 21 is dated 30NOV2020 in EDC, however the same is dated as 01DEC2020in PPD Central lab. Please review the appropriate date and visit and update accordingly in EDC or in PPD lab via DCF. Thanks ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 09:42:07
Query 'Per GCL Lab Reconciliation: Saliva: Sample recorded under Illness Visit Day 21 is dated 30NOV2020 in EDC, however the same is dated as 01DEC2020in PPD Central lab. Please review the appropriate date and visit and update accordingly in EDC or in PPD lab via DCF. Thanks ' answered with 'Date collected is 30 NOV 2020 which is what is entered in electronic requisition form created in PPD as well. ' (Site from DM).	Alexandra Caillouet (b) (4)	05 Apr 2021 20:22:04
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample recorded under Illness Visit Day 21 is dated 30NOV2020 in EDC, however the same is dated as 01DEC2020in PPD Central lab. Please review the appropriate date and visit and update accordingly in EDC or in PPD lab via DCF. Thanks ' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 05:33:03
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 01DEC2020 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)	02 Feb 2021 10:01:42

US3362125

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:17:16

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30NOV2020 is recorded under Illness Visit Day 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)	02 Feb 2021 10:01:40
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 01DEC2020 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 'Day 21 Saliva was collected on 30 Nov 2020. AWB Number: 939474275870 Accession Number: 1F67709 ' (Site from DM).	Alexandra Caillouet (b) (4)	01 Feb 2021 20:20:56
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 01DEC2020 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)	01 Feb 2021 06:57:54
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30NOV2020 is recorded under Illness Visit Day 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: 1F67709 ' (Site from DM).	Alexandra Caillouet (b) (4)	29 Jan 2021 21:35:22

US3362125

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:17:16

Date of Collection

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30NOV2020 is recorded under Illness Visit Day 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)	29 Jan 2021 04:45:09
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 01DEC2020 is recorded under Illness Visit Day 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)	19 Jan 2021 07:49:51
User entered '30 Nov 2020' reason for change: Data Entry Error	Amy Thomassie (b) (4)	08 Jan 2021 22:31:50
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 01DEC2020 is recorded under Illness Visit Day 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: 1F67709' (Site from DM).	Alexandra Caillouet (b) (4)	07 Jan 2021 17:05:06
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 01DEC2020 is recorded under Illness Visit Day 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)	06 Jan 2021 04:50:23
User entered '01 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Dec 2020 16:35:41
User entered '01 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Dec 2020 16:34:27

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3362125

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:17:16

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '30 Nov 2020' reason for change: Data Entry Error	Alexandra Caillouet	24 Dec 2020 15:30:49
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 02DEC2020 is reported under Convalescence 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)	21 Dec 2020 10:18:20
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 02DEC2020 is reported under Convalescence 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 'day 21 salvia collected on 29Nov2020, report of results on 30Nov 2020' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 16:58:25
User entered '29 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Dec 2020 16:57:50
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 02DEC2020 is reported under Convalescence 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)	18 Dec 2020 06:50:50
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 07DEC2020 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. ' canceled (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 06:50:09
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 07DEC2020 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)	18 Dec 2020 06:42:09

PRODUCTION RELEASE (v12.003
EAB) (1725)

2116 of 2664

US3362125

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:17:16

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '30 Nov 2020' reason for change: Data Entry Error	Alexandra Caillouet	10 Dec 2020 21:26:51
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:01:22

US3362125

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:17:16

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:47
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 07DEC2020 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)	19 Jan 2021 07:50:01
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 07DEC2020 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 'updated' (Site from DM).	Amy Thomassie (b) (4) (b) (4)	08 Jan 2021 22:32:10
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 07DEC2020 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)	08 Jan 2021 04:16:22
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	12 Nov 2020 18:01:22

US3362125

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:17:16

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:47
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	12 Apr 2021 19:20:56
User entered 'Yes (Y)' reason for change: Data Entry Error	Alexandra Caillouet	21 Dec 2020 16:07:44
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	13 Nov 2020 08:54:17
Query 'Data is required. Please complete.' answered with 'pending' (Site from System).	(b) (4), (b) (6)	12 Nov 2020 18:02:29
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 18:01:22
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 18:01:22

US3362125

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:17:16

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:47
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:20:56
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 08DEC2020 is recorded under Illness Visit Day 28 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)	19 Jan 2021 07:50:03
User entered '07 Dec 2020' reason for change: Data Entry Error	Amy Thomassie (b) (4)	08 Jan 2021 22:31:50
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 08DEC2020 is recorded under Illness Visit Day 28 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: 1F67709' (Site from DM).	Alexandra Caillouet (b) (4)	07 Jan 2021 17:03:46
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 08DEC2020 is recorded under Illness Visit Day 28 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)	06 Jan 2021 04:50:53
User entered '08 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Dec 2020 16:35:17
User entered '7 Dec 2020' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	21 Dec 2020 16:07:44
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 18:01:22

US3362125

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:17:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:16
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:53:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Nov 2020 18:16:09

US3362125

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:16
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:53:05
User entered '9 Nov 2020'	(b) (4), (b) (6)	09 Nov 2020 18:16:09

US3362125

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:17:16

[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 04:28:16
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:53:05
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	09 Nov 2020 18:16:09

US3362125

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:17:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:16
User entered 'SICKD1'	System	09 Nov 2020 18:16:09

US3362125

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:26
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:53:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Nov 2020 18:17:50

US3362125

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:26
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:53:36
User entered '9 Nov 2020'	(b) (4), (b) (6)	09 Nov 2020 18:17:50

US3362125

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:26
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:53:36
User entered '11:05'	(b) (4), (b) (6)	09 Nov 2020 18:17:50

US3362125

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:26
User entered '9 Nov 2020 11:05'	System	09 Nov 2020 18:17:50

US3362125

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:26
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:53:36
User entered '183' cm	(b) (4), (b) (6)	09 Nov 2020 18:17:50
DataPoint set to visible.	System	09 Nov 2020 18:16:09

US3362125

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:26
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:53:36
User entered '96.9' kg	(b) (4), (b) (6)	09 Nov 2020 18:17:50
DataPoint set to visible.	System	09 Nov 2020 18:16:09

US3362125

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:26
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:53:36
User entered '37.0' C	(b) (4), (b) (6)	09 Nov 2020 18:17:50

US3362125

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:26
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:53:36
User entered 'Oral (Oral)'	(b) (4), (b) (6)	09 Nov 2020 18:17:50

US3362125

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:26
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:53:36
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 18:17:50

US3362125

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:26
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:53:36
User entered '76'	(b) (4), (b) (6)	09 Nov 2020 18:17:50

US3362125

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:26
User entered 'bpm'	System	09 Nov 2020 18:17:50

US3362125

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:26
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:53:36
User entered '17'	(b) (4), (b) (6)	09 Nov 2020 18:17:50

US3362125

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:26
User entered 'breaths/min'	System	09 Nov 2020 18:17:50

US3362125

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:26
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:53:36
User entered '145' reason for change: Data Entry Error	Crystal Rowell (b) (4)	13 Nov 2020 18:31:13
User entered '148'	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:17:50

US3362125

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:26
User entered 'mmHg'	System	09 Nov 2020 18:17:50

US3362125

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:26
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:53:36
User entered '92' reason for change: Data Entry Error	Crystal Rowell (b) (4)	13 Nov 2020 18:31:13
User entered '96'	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:17:50

US3362125

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:26
User entered 'mmHg'	System	09 Nov 2020 18:17:50

US3362125

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:26

US3362125

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:26

US3362125

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:17:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:32
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:53:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Nov 2020 18:17:58

US3362125

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:17:16

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:32
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:53:43
User entered '9 Nov 2020'	(b) (4), (b) (6)	09 Nov 2020 18:17:58

US3362125

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 17:17:16

[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 04:28:38
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:53:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Nov 2020 18:18:04

US3362125

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 17:17:16

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:38
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:53:48
User entered '9 Nov 2020'	(b) (4), (b) (6)	09 Nov 2020 18:18:04

US3362125

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:17:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:19:07
User closed query 'Per GCL Lab Reconciliation: Swab: Re-query: Previous query response indicates, "no swab collected for illness day 28 visit", however, GCL has a Swab sample with a Collection Date of 07DEC2020. Please enter this Swab sample in the Covid-19 Assessment folder, as appropriate.' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 05:48:44
Query 'Per GCL Lab Reconciliation: Swab: Re-query: Previous query response indicates, "no swab collected for illness day 28 visit", however, GCL has a Swab sample with a Collection Date of 07DEC2020. Please enter this Swab sample in the Covid-19 Assessment folder, as appropriate.' answered with 'No swab was collected on 07 DEC 2020. Only Immunologic blood sample was collected for this Day 28 visit.' (Site from DM).	Alexandra Caillouet (b) (4)	30 Dec 2020 20:55:22
User opened query 'Per GCL Lab Reconciliation: Swab: Re-query: Previous query response indicates, "no swab collected for illness day 28 visit", however, GCL has a Swab sample with a Collection Date of 07DEC2020. Please enter this Swab sample in the Covid-19 Assessment folder, as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 22:18:33
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 07DEC2020 is recorded under Convalescence Visit Day 28 in GCL, however, the swab sample for 07DEC2020 is missing in EDC. Please confirm if this sample should be recorded in the Covid-19 Assessment folder and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 22:18:33

US3362125

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:17:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 07DEC2020 is recorded under Convalescence Visit Day 28 in GCL, however, the swab sample for 07DEC2020 is missing in EDC. Please confirm if this sample should be recorded in the Covid-19 Assessment folder and update as appropriate. ' answered with 'no swab collected for illness day 28 visit' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 18:52:34
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 07DEC2020 is recorded under Convalescence Visit Day 28 in GCL, however, the swab sample for 07DEC2020 is missing in EDC. Please confirm if this sample should be recorded in the Covid-19 Assessment folder and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 17:50:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Dec 2020 16:23:49

US3362125

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:17:16

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:19:07
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 07DEC2020 for Day 28 is reported under Illness visit in PPD central lab, however sample details are not recorded in EDC. Please update as appropriate, thank you.' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 04:23:51
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 07DEC2020 for Day 28 is reported under Illness visit in PPD central lab, however sample details are not recorded in EDC. Please update as appropriate, thank you.' answered with 'Added.' (Site from DM).	Alexandra Caillouet (b) (4)	21 Dec 2020 16:07:54
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 07DEC2020 for Day 28 is reported under Illness visit in PPD central lab, however sample details are not recorded in EDC. Please update as appropriate, thank you.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 10:19:41
User entered '7 Dec 2020'	(b) (4), (b) (6)	07 Dec 2020 16:23:49

US3362125

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:17:16

[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 21:25:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:19:07
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	07 Dec 2020 16:23:49

US3362125

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:17:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:57
User entered 'SICKD28'	System	07 Dec 2020 16:23:49

US3362125

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:19:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Dec 2020 16:35:03

US3362125

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:19:29
User entered '7 Dec 2020'	(b) (4), (b) (6)	07 Dec 2020 16:35:03

US3362125

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:19:29
User entered '09:35'	(b) (4), (b) (6)	07 Dec 2020 16:35:03

US3362125

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:57
User entered '7 Dec 2020 09:35'	System	07 Dec 2020 16:35:03

US3362125

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:19:29
User entered '183' cm	(b) (4), (b) (6)	07 Dec 2020 16:35:03
DataPoint set to visible.	System	07 Dec 2020 16:23:49

US3362125

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:19:29
User entered '96.9' kg	(b) (4), (b) (6)	07 Dec 2020 16:35:03
DataPoint set to visible.	System	07 Dec 2020 16:23:49

US3362125

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:19:29
User entered '36.7' C	(b) (4), (b) (6)	07 Dec 2020 16:35:03

US3362125

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:19:29
User entered 'Oral (Oral)'	(b) (4), (b) (6)	07 Dec 2020 16:35:03

US3362125

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:19:29
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 16:35:03

US3362125

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:19:29
User entered '56'	(b) (4), (b) (6)	07 Dec 2020 16:35:03

US3362125

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:57
User entered 'bpm'	System	07 Dec 2020 16:35:03

US3362125

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:19:29
User entered '16'	(b) (4), (b) (6)	07 Dec 2020 16:35:03

US3362125

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:57
User entered 'breaths/min'	System	07 Dec 2020 16:35:03

US3362125

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:19:29
User entered '137'	(b) (4), (b) (6)	07 Dec 2020 16:35:03

US3362125

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:57
User entered 'mmHg'	System	07 Dec 2020 16:35:03

US3362125

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:19:29
User entered '90'	(b) (4), (b) (6)	07 Dec 2020 16:35:03

US3362125

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:57
User entered 'mmHg'	System	07 Dec 2020 16:35:03

US3362125

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:57

US3362125

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:57

US3362125

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:17:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:19:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Dec 2020 16:35:12

US3362125

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:17:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:19:42
User entered '7 Dec 2020'	(b) (4), (b) (6)	07 Dec 2020 16:35:12

US3362125

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 09 Jun 2021 17:17:16

[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 21:25:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:19:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Dec 2020 16:36:04

US3362125

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 09 Jun 2021 17:17:16

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:19:47
User entered '7 Dec 2020'	(b) (4), (b) (6)	07 Dec 2020 16:36:04

US3362125

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

Form: Visit Date

Generated On: 09 Jun 2021 17:17:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:23:00
User entered 'Yes (Y)'	Alexandra Caillouet	22 Feb 2021 19:16:15
	(b) (4)	

US3362125

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

Form: Visit Date

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:23:00
User entered '22 Feb 2021'	Alexandra Caillouet	22 Feb 2021 19:16:15
	(b) (4)	

US3362125

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

Form: Visit Date

Generated On: 09 Jun 2021 17:17:16

[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 15:59:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:23:00
User entered 'Clinic (Clinic)'	Alexandra Caillouet	22 Feb 2021 19:16:15
	(b) (4)	

US3362125

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

Form: Visit Date

Generated On: 09 Jun 2021 17:17:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User entered 'UNBLND_DECIDE'	System	22 Feb 2021 19:16:15

US3362125

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

Form: Unblinding

Generated On: 09 Jun 2021 17:17:16

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:23:07
User entered '22 Feb 2021'	Alexandra Caillouet	22 Feb 2021 19:17:38
	(b) (4)	

US3362125

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

Form: Unblinding

Generated On: 09 Jun 2021 17:17:16

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 15:59:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
	(b) (4)	
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:29:22

US3362125

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

Form: Unblinding

Generated On: 09 Jun 2021 17:17:16

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:23:07
User entered 'Yes (Y)'	Alexandra Caillouet	22 Feb 2021 19:17:38
	(b) (4)	

US3362125

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

Form: Unblinding

Generated On: 09 Jun 2021 17:17:16

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
	(b) (4)	
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:29:22

US3362125

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

Form: Unblinding

Generated On: 09 Jun 2021 17:17:16

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:23:07
User entered '22 Feb 2021'	Alexandra Caillouet	22 Feb 2021 19:17:38
	(b) (4)	

US3362125

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

Form: Unblinding

Generated On: 09 Jun 2021 17:17:16

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:23:07
User entered 'Placebo (Placebo)'	Alexandra Caillouet	22 Feb 2021 19:17:38
	(b) (4)	

US3362125

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

Form: Unblinding

Generated On: 09 Jun 2021 17:17:16

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:23:07
User entered 'Placebo (Placebo)'	Alexandra Caillouet	22 Feb 2021 19:17:38
	(b) (4)	

US3362125

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

Form: Unblinding

Generated On: 09 Jun 2021 17:17:16

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:23:07
User entered 'Placebo (Placebo)'	Alexandra Caillouet	22 Feb 2021 19:17:38
	(b) (4)	

US3362125

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

Form: Unblinding

Generated On: 09 Jun 2021 17:17:16

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:23:07
User entered 'Yes (Y)'	Alexandra Caillouet	22 Feb 2021 19:17:38
	(b) (4)	

US3362125

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

Form: Unblinding

Generated On: 09 Jun 2021 17:17:16

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User entered 'I'	System	22 Feb 2021 19:17:38

US3362125

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

Form: Unblinding

Generated On: 09 Jun 2021 17:17:16

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User entered 'I'	System	22 Feb 2021 19:17:38

US3362125

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:17:16

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:24:04
User entered missing code ND - Not Done.	Alexandra Caillouet	22 Feb 2021 19:23:11
	(b) (4)	

US3362125

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:17:16

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:24:04
User entered missing code ND - Not Done.	Alexandra Caillouet	22 Feb 2021 19:23:11
	(b) (4)	

US3362125

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:17:16

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User entered empty.	System	22 Feb 2021 19:23:11
DataPoint set to visible.	System	22 Feb 2021 19:17:38

US3362125

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:17:16

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:24:04
User entered missing code ND - Not Done.	Alexandra Caillouet	22 Feb 2021 19:23:11
	(b) (4)	

US3362125

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:17:16

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:24:04
User entered missing code ND - Not Done.	Alexandra Caillouet	22 Feb 2021 19:23:11
	(b) (4)	

US3362125

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:17:16

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User entered empty.	System	22 Feb 2021 19:23:11
DataPoint set to visible.	System	22 Feb 2021 19:17:38

US3362125

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User accepted default value 'Pre-Dose (PREDOSE)'	Alexandra Caillouet	22 Feb 2021 19:23:11
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:24:04
User entered 'Yes (Y)'	Alexandra Caillouet	22 Feb 2021 19:23:11
	(b) (4)	

US3362125

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:24:04
User entered '22 Feb 2021'	Alexandra Caillouet	22 Feb 2021 19:23:11
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:24:04
User entered '09:59'	Alexandra Caillouet	22 Feb 2021 19:23:11
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User entered '22 Feb 2021 09:59'	System	22 Feb 2021 19:23:11

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:24:04
User entered '36.9' C	Alexandra Caillouet	22 Feb 2021 19:23:11
	(b) (4)	

US3362125

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:24:04
User entered 'Oral (Oral)'	Alexandra Caillouet	22 Feb 2021 19:23:11
	(b) (4)	

US3362125

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:24:04
User entered empty.	Alexandra Caillouet	22 Feb 2021 19:23:11
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:24:04
User entered '52'	Alexandra Caillouet	22 Feb 2021 19:23:11
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User entered 'bpm'	System	22 Feb 2021 19:23:11

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:24:04
User entered '18'	Alexandra Caillouet	22 Feb 2021 19:23:11
	(b) (4)	

US3362125

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User entered 'breaths/min'	System	22 Feb 2021 19:23:11

US3362125

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:24:04
User entered '160'	Alexandra Caillouet	22 Feb 2021 19:23:11
	(b) (4)	

US3362125

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User entered 'mmHg'	System	22 Feb 2021 19:23:11

US3362125

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:24:04
User entered '93'	Alexandra Caillouet	22 Feb 2021 19:23:11
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User entered 'mmHg'	System	22 Feb 2021 19:23:11

US3362125

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:17:16

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:24:04
User entered missing code ND - Not Done.	Alexandra Caillouet	22 Feb 2021 19:23:11
	(b) (4)	

US3362125

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:17:16

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:24:04
User entered missing code ND - Not Done.	Alexandra Caillouet	22 Feb 2021 19:23:11
	(b) (4)	

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:17:16

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User entered empty.	System	22 Feb 2021 19:23:11
DataPoint set to visible.	System	22 Feb 2021 19:17:38

US3362125

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User accepted default value 'Post-Dose (POSTDOSE)'	Alexandra Caillouet	22 Feb 2021 19:23:11
	(b) (4)	

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:24:04
User entered 'Yes (Y)'	Alexandra Caillouet	22 Feb 2021 19:23:11
	(b) (4)	

US3362125

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:24:04
User entered '22 Feb 2021'	Alexandra Caillouet	22 Feb 2021 19:23:11
	(b) (4)	

US3362125

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:24:04
User entered '11:02'	Alexandra Caillouet	22 Feb 2021 19:23:11
	(b) (4)	

US3362125

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User entered '22 Feb 2021 11:02'	System	22 Feb 2021 19:23:11

US3362125

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:24:04
User entered '36.8' C	Alexandra Caillouet	22 Feb 2021 19:23:11
	(b) (4)	

US3362125

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:24:04
User entered 'Oral (Oral)'	Alexandra Caillouet	22 Feb 2021 19:23:11
	(b) (4)	

US3362125

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:24:04
User entered empty.	Alexandra Caillouet	22 Feb 2021 19:23:11
	(b) (4)	

US3362125

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:24:04
User entered '64'	Alexandra Caillouet	22 Feb 2021 19:23:11
	(b) (4)	

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User entered 'bpm'	System	22 Feb 2021 19:23:11

US3362125

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:24:04
User entered '18'	Alexandra Caillouet	22 Feb 2021 19:23:11
	(b) (4)	

US3362125

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User entered 'breaths/min'	System	22 Feb 2021 19:23:11

US3362125

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:24:04
User entered '161'	Alexandra Caillouet	22 Feb 2021 19:23:11
	(b) (4)	

US3362125

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User entered 'mmHg'	System	22 Feb 2021 19:23:11

US3362125

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:24:04
User entered '86'	Alexandra Caillouet	22 Feb 2021 19:23:11
	(b) (4)	

US3362125

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User entered 'mmHg'	System	22 Feb 2021 19:23:11

US3362125

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:17:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:24:22
User entered 'No (N)'	Alexandra Caillouet	22 Feb 2021 19:23:31
	(b) (4)	

US3362125

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:17:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:24:22
User entered empty.	Alexandra Caillouet	22 Feb 2021 19:23:31
	(b) (4)	

US3362125

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

Form: Exposure

Generated On: 09 Jun 2021 17:17:16

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:24:37
User entered 'Yes (Y)'	Alexandra Caillouet	22 Feb 2021 19:23:52
	(b) (4)	

US3362125

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

Form: Exposure

Generated On: 09 Jun 2021 17:17:16

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:24:37
User entered empty.	Alexandra Caillouet	22 Feb 2021 19:23:52
	(b) (4)	

US3362125

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

Form: Exposure

Generated On: 09 Jun 2021 17:17:16

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 15:59:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:24:37
User entered empty.	Alexandra Caillouet	22 Feb 2021 19:23:52
	(b) (4)	

US3362125

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

Form: Exposure

Generated On: 09 Jun 2021 17:17:16

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User entered 'mRNA-1273'	System	22 Feb 2021 19:23:52
DataPoint set to visible.	System	22 Feb 2021 19:17:38

US3362125

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

Form: Exposure

Generated On: 09 Jun 2021 17:17:16

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:24:37
User entered '22 Feb 2021'	Alexandra Caillouet	22 Feb 2021 19:23:52
	(b) (4)	

US3362125

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

Form: Exposure

Generated On: 09 Jun 2021 17:17:16

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:24:37
User entered '10:22'	Alexandra Caillouet	22 Feb 2021 19:23:52
	(b) (4)	

US3362125

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

Form: Exposure

Generated On: 09 Jun 2021 17:17:16

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User entered '22 Feb 2021 10:22'	System	22 Feb 2021 19:23:52

US3362125

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

Form: Exposure

Generated On: 09 Jun 2021 17:17:16

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:24:37
User entered 'Left Arm (LEFT ARM)'	Alexandra Caillouet	22 Feb 2021 19:23:52
	(b) (4)	

US3362125

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

Form: Exposure

Generated On: 09 Jun 2021 17:17:16

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:24:37
User entered 'ONCE'	System	22 Feb 2021 19:23:52

US3362125

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

Form: Exposure

Generated On: 09 Jun 2021 17:17:16

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User entered 'INTRAMUSCULAR'	System	22 Feb 2021 19:23:52

US3362125

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:17:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:25:27
User entered 'Yes (Y)'	Alexandra Caillouet	22 Feb 2021 19:16:28
	(b) (4)	

US3362125

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:17:16

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:25:27
User entered '22 Feb 2021'	Alexandra Caillouet	22 Feb 2021 19:16:28
	(b) (4)	

US3362125

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:17:16

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:25:27
User entered '09:47'	Alexandra Caillouet	22 Feb 2021 19:16:28
	(b) (4)	

US3362125

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:17:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User entered '22 Feb 2021 09:47'	System	22 Feb 2021 19:16:28

US3362125

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:17:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:25:35
User entered 'Yes (Y)'	Alexandra Caillouet	22 Feb 2021 19:16:39
	(b) (4)	

US3362125

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:17:16

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:25:35
User entered '22 Feb 2021'	Alexandra Caillouet	22 Feb 2021 19:16:39
	(b) (4)	

US3362125

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:17:16

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:25:35
User entered '09:50'	Alexandra Caillouet	22 Feb 2021 19:16:39
	(b) (4)	

US3362125

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:17:16

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User entered '22 Feb 2021 09:50'	System	22 Feb 2021 19:16:39

US3362125

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

Form: Continuing

Generated On: 09 Jun 2021 17:17:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:25:44
User entered 'Yes (Y)'	Alexandra Caillouet	22 Feb 2021 19:24:06
	(b) (4)	

US3362125

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

Form: Continuing

Generated On: 09 Jun 2021 17:17:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:41
User entered 'I'	System	22 Feb 2021 19:24:06

US3362125

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:16

[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 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:25:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Mar 2021 15:08:25

US3362125

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:16

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 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:25:55
User entered '1 Mar 2021'	(b) (4), (b) (6)	02 Mar 2021 15:08:25

US3362125

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:16

[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 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:25:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	02 Mar 2021 15:08:25

US3362125

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:16

[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 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:25:55
User entered empty.	(b) (4), (b) (6)	02 Mar 2021 15:08:25

US3362125

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:16

[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 00:17:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:26:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Mar 2021 15:08:30

US3362125

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:44
User entered 'I'	System	02 Mar 2021 15:08:30

US3362125

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:16

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:44
User entered 'I'	System	02 Mar 2021 15:08:30
DataPoint set to visible.	System	02 Mar 2021 15:08:30

US3362125

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:17:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:11
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	22 Mar 2021 15:55:20

US3362125

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:11
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered '22 Mar 2021'	Alexandra Caillouet (b) (4)	22 Mar 2021 15:55:20

US3362125

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:17:16

[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 11:32:11
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered 'Clinic (Clinic)'	Alexandra Caillouet (b) (4)	22 Mar 2021 15:55:20

US3362125

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:17:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:11
User entered 'OLD29'	System	22 Mar 2021 15:55:20

US3362125

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:11
User accepted default value 'Pre-Dose (PREDOSE)'	Alexandra Caillouet (b) (4)	22 Mar 2021 16:07:13

US3362125

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:11
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	22 Mar 2021 16:07:13

US3362125

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:11
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered '22 Mar 2021'	Alexandra Caillouet (b) (4)	22 Mar 2021 16:07:13

US3362125

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:11
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered '09:55'	Alexandra Caillouet (b) (4)	22 Mar 2021 16:07:13

US3362125

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:11
User entered '22 Mar 2021 09:55'	System	22 Mar 2021 16:07:13

US3362125

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:11
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered '36.8' C	Alexandra Caillouet (b) (4)	22 Mar 2021 16:07:13

US3362125

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:11
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered 'Oral (Oral)'	Alexandra Caillouet (b) (4)	22 Mar 2021 16:07:13

US3362125

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:11
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered empty.	Alexandra Caillouet (b) (4)	22 Mar 2021 16:07:13

US3362125

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:11
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered '67'	Alexandra Caillouet (b) (4)	22 Mar 2021 16:07:13

US3362125

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:11
User entered 'bpm'	System	22 Mar 2021 16:07:13

US3362125

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:11
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered '18'	Alexandra Caillouet (b) (4)	22 Mar 2021 16:07:13

US3362125

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:11
User entered 'breaths/min'	System	22 Mar 2021 16:07:13

US3362125

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:11
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered '142'	Alexandra Caillouet (b) (4)	22 Mar 2021 16:07:13

US3362125

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:11
User entered 'mmHg'	System	22 Mar 2021 16:07:13

US3362125

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:11
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered '93'	Alexandra Caillouet (b) (4)	22 Mar 2021 16:07:13

US3362125

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:11
User entered 'mmHg'	System	22 Mar 2021 16:07:13

US3362125

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:11
User accepted default value 'Post-Dose (POSTDOSE)'	Alexandra Caillouet (b) (4)	22 Mar 2021 16:07:13

US3362125

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:11
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	22 Mar 2021 16:07:13

US3362125

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:11
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered '22 Mar 2021'	Alexandra Caillouet (b) (4)	22 Mar 2021 16:07:13

US3362125

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:11
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered '11:05'	Alexandra Caillouet (b) (4)	22 Mar 2021 16:07:13

US3362125

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:11
User entered '22 Mar 2021 11:05'	System	22 Mar 2021 16:07:13

US3362125

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:11
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered '36.5' C	Alexandra Caillouet (b) (4)	22 Mar 2021 16:07:13

US3362125

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:11
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered 'Oral (Oral)'	Alexandra Caillouet (b) (4)	22 Mar 2021 16:07:13

US3362125

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:11
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered empty.	Alexandra Caillouet (b) (4)	22 Mar 2021 16:07:13

US3362125

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:11
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered '65'	Alexandra Caillouet (b) (4)	22 Mar 2021 16:07:13

US3362125

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:11
User entered 'bpm'	System	22 Mar 2021 16:07:13

US3362125

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:11
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered '18'	Alexandra Caillouet (b) (4)	22 Mar 2021 16:07:13

US3362125

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:11
User entered 'breaths/min'	System	22 Mar 2021 16:07:13

US3362125

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:11
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered '143'	Alexandra Caillouet (b) (4)	22 Mar 2021 16:07:13

US3362125

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:11
User entered 'mmHg'	System	22 Mar 2021 16:07:13

US3362125

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:11
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered '90'	Alexandra Caillouet (b) (4)	22 Mar 2021 16:07:13

US3362125

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:11
User entered 'mmHg'	System	22 Mar 2021 16:07:13

US3362125

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:17:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:11
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	22 Mar 2021 15:55:49

US3362125

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:17:16

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:11
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered '22 Mar 2021'	Alexandra Caillouet (b) (4)	22 Mar 2021 15:55:49

US3362125

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:16

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:11
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	22 Mar 2021 15:56:09

US3362125

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:16

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:11
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered empty.	Alexandra Caillouet (b) (4)	22 Mar 2021 15:56:09

US3362125

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:16

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 11:32:11
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered empty.	Alexandra Caillouet (b) (4)	22 Mar 2021 15:56:09

US3362125

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:16

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:11
User entered 'mRNA-1273'	System	22 Mar 2021 15:56:09
DataPoint set to visible.	System	02 Mar 2021 15:08:30

US3362125

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:16

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:11
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered '22 Mar 2021'	Alexandra Caillouet (b) (4)	22 Mar 2021 15:56:09

US3362125

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:16

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:11
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered '10:33'	Alexandra Caillouet (b) (4)	22 Mar 2021 15:56:09

US3362125

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:16

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:11
User entered '22 Mar 2021 10:33'	System	22 Mar 2021 15:56:09

US3362125

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:16

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:11
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered 'Left Arm (LEFT ARM)'	Alexandra Caillouet (b) (4)	22 Mar 2021 15:56:09

US3362125

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:16

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:11
User entered 'ONCE'	System	22 Mar 2021 15:56:09

US3362125

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:16

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:11
User entered 'INTRAMUSCULAR'	System	22 Mar 2021 15:56:09

US3362125

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:11
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	22 Mar 2021 15:56:15

US3362125

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:32:11
User entered 'I'	System	22 Mar 2021 15:56:15

US3362125

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:02:00

US3362125

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
	(b) (4)	
User entered '29 Mar 2021'	(b) (4), (b) (6)	29 Mar 2021 21:02:00

US3362125

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:02:00

US3362125

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:02:00

US3362125

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:02:05

US3362125

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:16

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Mar 2021 21:02:05

US3362125

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:17:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:07:45

US3362125

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered '19 Apr 2021'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:07:45

US3362125

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:07:45

US3362125

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:17:16

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	19 Apr 2021 14:07:45

US3362125

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 14:08:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Apr 2021 14:08:19
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 14:08:19
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 14:08:11
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 14:08:11

US3362125

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:08:11

US3362125

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:08:11

US3362125

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 14:08:11

US3362125

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:08:11

US3362125

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:08:11

US3362125

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:08:11

US3362125

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:08:11

US3362125

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 14:08:11

US3362125

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

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

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:08:11

US3362125

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 14:08:11

US3362125

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:08:11

US3362125

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 14:08:11

US3362125

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:08:11

US3362125

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 14:08:11

US3362125

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:17:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:08:03

US3362125

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:17:16

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:08:03

US3362125

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:17:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:07:58

US3362125

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:17:16

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered '19 Apr 2021'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:07:58

US3362125

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:17:16

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
User entered '09:04'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:07:58

US3362125

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:17:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '19 Apr 2021 09:04'	System	19 Apr 2021 14:07:58

US3362125

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:17:16

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:00:22
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:56:37
User entered 'Yes (Y)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	13 Nov 2020 15:50:03
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	29 Aug 2020 13:32:38

US3362125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:16

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:57:16
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:55:26
User entered		
'USA-US112-2020-mRNA-1273-P301000010'	System	16 Nov 2020 16:55:14
User entered 'New'	(b) (4), (b) (6)	16 Nov 2020 16:55:14

US3362125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:16

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:14:00
User closed query 'PV Query: Please consider updating the event term to COVID-19.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 18:29:15
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 01:15:57
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)	20 Nov 2020 21:13:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Nov 2020 21:13:03
Data point term sent to Coder	System	20 Nov 2020 21:12:23
Query 'PV Query: Please consider updating the event term to COVID-19.' answered with 'updated' (Site from Safety).	Crystal Rowell (b) (4) (b) (4)	20 Nov 2020 21:11:35
DataPoint Un-verified.	Crystal Rowell (b) (4) (b) (4)	20 Nov 2020 21:11:25
Coding entries removed.	Crystal Rowell (b) (4) (b) (4)	20 Nov 2020 21:11:25
User entered 'COVID-19' reason for change: Data Entry Error	Crystal Rowell (b) (4) (b) (4)	20 Nov 2020 21:11:25
User opened query 'PV Query: Please consider updating the event term to COVID-19.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 15:21:53
User closed query 'Per CDM: Adverse event term reported as 'SARS COV2 POSITIVE', However please confirm if this condition is COVID-19 infection and update accordingly to capture the condition.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 07:27:58
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:57:16
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)	18 Nov 2020 21:44:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 21:44:48
Data point term sent to Coder	System	18 Nov 2020 21:29:01

US3362125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:16

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per CDM: Adverse event term reported as 'SARS COV2 POSITIVE', However please confirm if this condition is COVID-19 infection and update accordingly to capture the condition.' answered with 'ICD-10 code for Symptomatic Covid-19 is U07.1' (Site from DM). Coding entries removed.	Alexandra Caillouet (b) (4)	18 Nov 2020 21:28:21
User entered 'Symptomatic Covid-19' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	18 Nov 2020 21:28:15
User opened query 'Per CDM: Adverse event term reported as 'SARS COV2 POSITIVE', However please confirm if this condition is COVID-19 infection and update accordingly to capture the condition.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 12:01:33
User coded data point as SOC: Investigations, HLGT: Microbiology and serology investigations, HLT: Virus identification and serology, PT: SARS-CoV-2 test positive, LLT: SARS-CoV-2 test positive - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 15:57:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 15:57:46
Data point term sent to Coder	System	13 Nov 2020 15:56:37
User entered 'SARS COV-2 Positive'	Crystal Rowell (b) (4) (b) (4)	13 Nov 2020 15:55:53

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:16

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:57:16
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	13 Nov 2020 15:55:53
	(b) (4)	

US3362125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:16

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:57:16
User entered 'No (N)'	Crystal Rowell (b) (4)	13 Nov 2020 15:55:53
	(b) (4)	

US3362125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:16

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:14:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:57:16
User entered 'Yes (Y)'	Crystal Rowell (b) (4) (b) (4)	13 Nov 2020 15:55:53

US3362125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:14:00
User closed query 'PV Query: The start date of the event is 08 Nov 2020. Did the subject report any symptoms on that day? If yes, please add 08 Nov 2020 to the Covid-19 assessment symptom log in EDC.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 18:29:19
Query 'PV Query: The start date of the event is 08 Nov 2020. Did the subject report any symptoms on that day? If yes, please add 08 Nov 2020 to the Covid-19 assessment symptom log in EDC.' answered with 'symptom log has the 8th recorded' (Site from Safety).	Crystal Rowell (b) (4) (b) (4)	20 Nov 2020 21:13:46
User opened query 'PV Query: The start date of the event is 08 Nov 2020. Did the subject report any symptoms on that day? If yes, please add 08 Nov 2020 to the Covid-19 assessment symptom log in EDC.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 15:21:36
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:57:16
User entered '8 Nov 2020'	Crystal Rowell (b) (4) (b) (4)	13 Nov 2020 15:55:53

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:16

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:57:16
User entered empty.	Crystal Rowell (b) (4)	13 Nov 2020 15:55:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:16

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 15:55:53

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:14:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:21:39
DataPoint Un-verified.	Crystal Rowell (b) (4)	20 Nov 2020 21:12:43
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	20 Nov 2020 21:12:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:57:16
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	13 Nov 2020 15:55:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:14:00
User closed query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 18:29:22
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:21:42
Query 'PV Query: Please provide the event end date (when symptoms have resolved).' answered with 'updated' (Site from Safety).	Crystal Rowell (b) (4) (b) (4)	20 Nov 2020 21:12:58
DataPoint Un-verified.	Crystal Rowell (b) (4) (b) (4)	20 Nov 2020 21:12:43
User entered '13 Nov 2020' reason for change: Data Entry Error	Crystal Rowell (b) (4) (b) (4)	20 Nov 2020 21:12:43
User opened query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 15:21:11
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:57:16
User entered empty.	Crystal Rowell (b) (4) (b) (4)	13 Nov 2020 15:55:53

US3362125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:16

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:57:16
User entered empty.	Crystal Rowell (b) (4)	13 Nov 2020 15:55:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:16

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 15:55:53

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:16

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:14:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:57:16
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Crystal Rowell (b) (4) (b) (4)	13 Nov 2020 15:55:53

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:57:16
User entered 'No (N)'	Crystal Rowell (b) (4)	13 Nov 2020 15:55:53
	(b) (4)	

US3362125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:57:16
User entered '0'	Crystal Rowell (b) (4)	13 Nov 2020 15:55:53
	(b) (4)	

US3362125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:57:16
User entered '0'	Crystal Rowell (b) (4)	13 Nov 2020 15:55:53
	(b) (4)	

US3362125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:57:16
User entered '0'	Crystal Rowell (b) (4)	13 Nov 2020 15:55:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:16

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:57:16
User entered empty.	Crystal Rowell (b) (4)	13 Nov 2020 15:55:53
	(b) (4)	

US3362125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:16

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:57:16
User entered empty.	Crystal Rowell (b) (4)	13 Nov 2020 15:55:53
	(b) (4)	

US3362125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:16

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:57:16
User entered empty.	Crystal Rowell (b) (4)	13 Nov 2020 15:55:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:16

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:57:16
User entered empty.	Crystal Rowell (b) (4)	13 Nov 2020 15:55:53
	(b) (4)	

US3362125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:57:16
User entered '0'	Crystal Rowell (b) (4)	13 Nov 2020 15:55:53
	(b) (4)	

US3362125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:57:16
User entered '0'	Crystal Rowell (b) (4)	13 Nov 2020 15:55:53
	(b) (4)	

US3362125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:57:16
User entered '0'	Crystal Rowell (b) (4)	13 Nov 2020 15:55:53
	(b) (4)	

US3362125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:16

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:57:16
User closed query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 11:38:03
Query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you ' answered with 'update' (Site from DM).	Alexandra Caillouet (b) (4)	18 Nov 2020 21:28:42
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	18 Nov 2020 21:28:15
User opened query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 07:57:08
User entered 'Not Applicable (NOT APPLICABLE)'	Crystal Rowell (b) (4) (b) (4)	13 Nov 2020 15:55:53

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:16

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:57:16
User entered 'Not Related (NOT RELATED)'	Alexandra Caillouet	18 Nov 2020 21:28:15
reason for change: Data Entry Error	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Crystal Rowell (b) (4)	13 Nov 2020 15:55:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:16

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:57:16
User entered 'Not Applicable (NOT APPLICABLE)'	Crystal Rowell (b) (4)	13 Nov 2020 15:55:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:16

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:27:37
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:14:00
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #4 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:27:27
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #4 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate. ' answered with 'updated' (Site from DM).	Alexandra Caillouet (b) (4)	11 Jan 2021 21:53:33
User entered '0' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	11 Jan 2021 21:53:27
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #4 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 05:11:41
User closed query 'None is checked, but Concomitant System Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).		08 Dec 2020 14:44:20
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	08 Dec 2020 14:44:13
DataPoint Un-verified.	(b) (4), (b) (6)	08 Dec 2020 14:44:13
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Dec 2020 14:44:13
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:57:16
User entered '0'	Crystal Rowell (b) (4) (b) (4)	13 Nov 2020 15:55:53

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Folder: Adverse Events

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:27:37
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:14:00
User entered '1' reason for change: Data Entry Error	(b) (4)	11 Jan 2021 21:53:27
DataPoint Un-verified.	Alexandra Caillouet (b) (4)	08 Dec 2020 14:44:20
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Dec 2020 14:44:20
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:57:16
User entered '1'	Crystal Rowell (b) (4)	13 Nov 2020 15:55:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:16

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:57:16
User entered '0'	Crystal Rowell (b) (4)	13 Nov 2020 15:55:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:14:00
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 18:29:27
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:33:43
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	Crystal Rowell (b) (4) (b) (4)	20 Nov 2020 21:13:57
DataPoint Un-verified.	Crystal Rowell (b) (4) (b) (4)	20 Nov 2020 21:12:43
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Crystal Rowell (b) (4) (b) (4)	20 Nov 2020 21:12:43
Data Entry Error		
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 15:20:49
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:57:16
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Crystal Rowell (b) (4) (b) (4)	13 Nov 2020 15:55:53

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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 22:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:57:16
User entered empty.	Crystal Rowell (b) (4)	13 Nov 2020 15:55:53
	(b) (4)	

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:14:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:57:16
User entered empty.	Crystal Rowell (b) (4)	13 Nov 2020 15:55:53
	(b) (4)	

US3362125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:16

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	13 Nov 2020 15:55:53

US3362125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:16

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Nov 2020 15:55:53

US3362125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:16

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:27:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 13:49:40
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:32
User entered	(b) (4)	19 Mar 2021 18:19:11
'USA-US112-2021-mRNA-1273-P301000015'	System	
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 18:19:11
User entered 'New' reason for change: Data Entry		19 Mar 2021 18:19:11
Error		
Reviewed for Safety.		19 Mar 2021 18:18:11
User entered		19 Mar 2021 18:13:17
'USA-US112-2020-mRNA-1273-P301000010'		

US3362125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:16

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:27:37
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:32
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Cardiac conduction disorders, PT: Atrioventricular block complete, LLT: AV block complete - version MedDRA\\23.0.	Coder Import (b) (4)	19 Mar 2021 07:28:02
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	19 Mar 2021 07:28:02
Data point term sent to Coder	System	18 Mar 2021 22:11:17
Coding entries removed.	Crystal Rowell (b) (4)	18 Mar 2021 22:10:57
User entered 'COMPLETE AV BLOCK' reason for change: Data Entry Error	Crystal Rowell (b) (4)	18 Mar 2021 22:10:57
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Cardiac conduction disorders, PT: Atrioventricular block complete, LLT: Complete heart block - version MedDRA\\23.0.	Coder Import (b) (4)	18 Mar 2021 21:52:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Mar 2021 21:52:56
Data point term sent to Coder	System	18 Mar 2021 21:52:19
User entered 'Complete Heart Block'	Crystal Rowell (b) (4)	18 Mar 2021 21:51:52

US3362125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:16

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:27:37
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:32
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	18 Mar 2021 21:51:52

US3362125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:16

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:27:37
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:32
User entered 'No (N)'	Crystal Rowell (b) (4)	18 Mar 2021 21:51:52

US3362125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:16

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:27:37
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:32
User entered 'No (N)'	Crystal Rowell (b) (4)	18 Mar 2021 21:51:52

US3362125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:27:37
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:32
User entered '17 Mar 2021'	Crystal Rowell (b) (4)	18 Mar 2021 21:51:52

US3362125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:16

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:27:37
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:32
User entered empty.	Crystal Rowell (b) (4)	18 Mar 2021 21:51:52

US3362125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:16

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Mar 2021 21:51:52

US3362125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:16

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:27:37
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:32
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Mar 2021 16:12:17
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	18 Mar 2021 21:51:52

US3362125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	14 Apr 2021 23:24:38
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:27:37
User closed query 'PV Query: Please consider updating event end date. Per Medical records, pacemaker was placed on 19 Mar 2021.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 14:39:54
Query 'PV Query: Please consider updating event end date. Per Medical records, pacemaker was placed on 19 Mar 2021.' answered with 'updated per query ' (Site from Safety).	Amy Thomassie (b) (4)	09 Apr 2021 14:47:41
Signature has been broken.	(b) (4)	
	Amy Thomassie (b) (4)	09 Apr 2021 14:47:25
User entered '19 Mar 2021' reason for change: Data Entry Error	(b) (4)	
	Amy Thomassie (b) (4)	09 Apr 2021 14:47:25
User opened query 'PV Query: Please consider updating event end date. Per Medical records, pacemaker was placed on 19 Mar 2021.' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 12:14:42
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 12:31:01
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:32
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'pacemaker placed on this date to correct the AV block AE' (Site from Safety).	(b) (4)	
	(b) (4), (b) (6)	26 Mar 2021 16:14:05
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	26 Mar 2021 16:12:51
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	26 Mar 2021 16:12:51

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	26 Mar 2021 16:12:17
User entered '18 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Mar 2021 16:12:17
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 15:48:51
User entered empty.	Crystal Rowell (b) (4)	18 Mar 2021 21:51:52

US3362125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:16

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:27:37
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:32
User entered empty.	Crystal Rowell (b) (4)	18 Mar 2021 21:51:52

US3362125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:16

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Mar 2021 21:51:52

US3362125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:16

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:27:37
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:32
User entered 'Grade 4 (Grade 4)'	Crystal Rowell (b) (4)	18 Mar 2021 21:51:52

US3362125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:27:37
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:32
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	18 Mar 2021 21:51:52

US3362125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:16

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:27:37
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:32
User entered '0'	Crystal Rowell (b) (4)	18 Mar 2021 21:51:52

US3362125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:16

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:27:37
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:32
User entered '0'	Crystal Rowell (b) (4)	18 Mar 2021 21:51:52

US3362125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:27:37
User closed query 'Per CDM: Please enter this data when it becomes available (or is confirmed to be unavailable). This query will remain open in the meantime. ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 16:46:55
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:32
Query 'Per CDM: Please enter this data when it becomes available (or is confirmed to be unavailable). This query will remain open in the meantime. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 16:13:33
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	22 Mar 2021 16:10:23
User opened query 'Per CDM: Please enter this data when it becomes available (or is confirmed to be unavailable). This query will remain open in the meantime. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 16:10:20
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'patient admitted on 17Mar2021 and will call when discharged- still in hospital ' (Site from System).	Crystal Rowell (b) (4)	18 Mar 2021 21:52:55
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	18 Mar 2021 21:51:52
User entered 'I'	Crystal Rowell (b) (4)	18 Mar 2021 21:51:52

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:16

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:27:37
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:32
User entered '17 Mar 2021'	Crystal Rowell (b) (4)	18 Mar 2021 21:51:52

US3362125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:16

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:27:37
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:32
User entered '20 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Mar 2021 16:12:17
User entered empty.	Crystal Rowell (b) (4)	18 Mar 2021 21:51:52

US3362125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:16

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:27:37
User closed query 'Per CDM: Please enter this data when it becomes available (or is confirmed to be unavailable). This query will remain open in the meantime. ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 16:46:53
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:32
Query 'Per CDM: Please enter this data when it becomes available (or is confirmed to be unavailable). This query will remain open in the meantime. ' answered with 'updated ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Mar 2021 16:13:13
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Mar 2021 16:12:17
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	(b) (4), (b) (6)	26 Mar 2021 16:08:38
User opened query 'Per CDM: Please enter this data when it becomes available (or is confirmed to be unavailable). This query will remain open in the meantime. ' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 16:08:34
Query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered with 'will follow up with patient to see if adminitted to ICU post pacemaker placement ' (Site from System).	Crystal Rowell (b) (4) (b) (4)	18 Mar 2021 21:52:16
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	18 Mar 2021 21:51:52
User entered 'Unknown (UNK)'	Crystal Rowell (b) (4) (b) (4)	18 Mar 2021 21:51:52

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:16

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:27:37
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:32
User entered empty.	Crystal Rowell (b) (4)	18 Mar 2021 21:51:52

US3362125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:27:37
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:32
User entered '0'	Crystal Rowell (b) (4)	18 Mar 2021 21:51:52

US3362125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:27:37
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:32
User entered '0'	Crystal Rowell (b) (4)	18 Mar 2021 21:51:52

US3362125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:16

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:27:37
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:32
User entered '0'	Crystal Rowell (b) (4)	18 Mar 2021 21:51:52

US3362125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:16

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:27:37
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:32
User entered 'Not Related (NOT RELATED)'	Crystal Rowell (b) (4)	18 Mar 2021 21:51:52

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:16

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:27:37
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:32
User entered 'Not Related (NOT RELATED)'	Crystal Rowell (b) (4)	18 Mar 2021 21:51:52

US3362125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:16

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:27:37
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:32
User entered 'None (NONE)'	Crystal Rowell (b) (4)	18 Mar 2021 21:51:52

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:16

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:27:37
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:32
User entered '0'	Crystal Rowell (b) (4)	18 Mar 2021 21:51:52

US3362125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:16

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, the ConMed #6 recorded was given AFTER the STOP date of this AE. Please review and reconcile AE and CM start dates as appropriate. Otherwise, clarify. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:33:16
Query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, the ConMed #6 recorded was given AFTER the STOP date of this AE. Please review and reconcile AE and CM start dates as appropriate. Otherwise, clarify. ' answered with 'CM # 6 was given as a prophylactic antibiotic following the pacemaker placement. ' (Site from DM).	Amy Thomassie (b) (4)	09 Apr 2021 14:53:47
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, the ConMed #6 recorded was given AFTER the STOP date of this AE. Please review and reconcile AE and CM start dates as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 05:27:27
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:32
User entered 'I'	Crystal Rowell (b) (4)	18 Mar 2021 21:51:52

US3362125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:16

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:27:37
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:32
User entered 'I'	Crystal Rowell (b) (4)	18 Mar 2021 21:51:52

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:16

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:27:37
User closed query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 12:31:54
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:32
Query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions' answered with 'updated' (Site from Safety).	(b) (4) (b) (4), (b) (6)	26 Mar 2021 16:14:23
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4), (b) (6)	26 Mar 2021 16:12:51
Data Entry Error		
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions' (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 15:49:12
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Crystal Rowell (b) (4) (b) (4)	18 Mar 2021 21:51:52

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Folder: Adverse Events

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:27:37
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:32
User entered empty.	Crystal Rowell (b) (4)	18 Mar 2021 21:51:52

US3362125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:16

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:27:37
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 14:39:59
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'Redacted records sent to Safety_Moderna@iqvia.com' (Site from Safety).	Alexandra Caillouet (b) (4)	09 Apr 2021 16:49:26
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 12:19:00
User closed query 'PV Query: Please provide any additional medication given for the event in addition to any surgical intervention. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 12:35:49
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 12:35:35
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 12:33:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:16

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety). User signature succeeded.	(b) (4), (b) (6)	29 Mar 2021 12:32:36
Query 'PV Query: Please provide the hospital discharge date when available.' answered with '03/20/2021' (Site from Safety).	Jordan Whatley (b) (4)	27 Mar 2021 00:09:32
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'will send record ' (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 16:11:34
Query 'PV Query: Please provide any additional medication given for the event in addition to any surgical intervention. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'updated ' (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 16:10:36
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'covid swab wasn't completed on this admit' (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 16:10:23
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 15:49:24

US3362125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:16

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 15:48:32
User opened query 'PV Query: Please provide any additional medication given for the event in addition to any surgical intervention. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 15:46:23
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 15:44:26
User entered 'Subjected contacted by sub-I to review history of elevated blood pressure, notified sub-I in hospital- had routine cardiology appointment and noted to have complete heart block, admitted for dual chamber pacemaker placement, will notify staff when discharged and will sign medical records release.'	Crystal Rowell (b) (4)	18 Mar 2021 21:51:52

US3362125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:16

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	18 Mar 2021 21:51:52

US3362125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:16

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	18 Mar 2021 21:51:52

US3362125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:16

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	18 Mar 2021 21:51:52

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:17:16

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:00:22
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:57:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 21:38:09

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:17:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:57:49
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTI-ACNE PREPARATIONS, ATC: ANTI-ACNE PREPARATIONS FOR TOPICAL USE, ATC: ANTIINFECTIVES FOR TREATMENT OF ACNE, PRODUCT: MINOCYCLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 11:56:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 11:56:01
Data point term sent to Coder	System	13 Aug 2020 21:39:35
User entered 'minocycline'	(b) (4), (b) (6)	13 Aug 2020 21:39:11

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:17:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:57:49
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 21:39:11

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:17:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:57:49
User closed query 'Per MM:Please revise the indication and/or route of administration.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 05:44:00
Query 'Per MM:Please revise the indication and/or route of administration.' answered with 'indication is confirmed as dermatitis' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 18:55:48
User opened query 'Per MM:Please revise the indication and/or route of administration.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 05:30:55
User entered 'dermatitis'	(b) (4), (b) (6)	13 Aug 2020 21:39:11

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:17:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:57:49
User closed query 'Per DM CLR: Please review the dose of this medication as this is not the standard dose. Reconcile and update as appropriate.	(b) (4), (b) (6)	09 Oct 2020 08:46:26
' (Site from DM).		
Query 'Per DM CLR: Please review the dose of this medication as this is not the standard dose. Reconcile and update as appropriate.	(b) (4), (b) (6)	18 Sep 2020 18:55:05
' answered with 'updated' (Site from DM).		
User entered '100' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 18:54:53
User opened query 'Per DM CLR: Please review the dose of this medication as this is not the standard dose. Reconcile and update as appropriate.	(b) (4), (b) (6)	17 Sep 2020 06:27:41
' (Site from DM).		
User entered '10'	(b) (4), (b) (6)	13 Aug 2020 21:39:11

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:17:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:57:49
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Aug 2020 21:39:11

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:17:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:57:49
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 21:39:11

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:17:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:57:49
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Aug 2020 21:39:11

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:17:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:57:49
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 21:39:11

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:17:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:57:49
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Aug 2020 21:39:11

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:17:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:57:49
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 21:39:11

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:17:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:57:49
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)	14 Aug 2020 12:00:31
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 21:39:11
User entered 'un UNK 2019'	(b) (4), (b) (6)	13 Aug 2020 21:39:11

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:57:49
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 21:39:11

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:17:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:57:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 21:39:11

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:17:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:57:49
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 21:39:11

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:17:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:57:49
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 21:39:11

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:17:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 21:39:11

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:17:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 21:39:11

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:17:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 21:39:11

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:17:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:57:49
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), COMBINATIONS, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS) AND DIURETICS, PRODUCT: HYDROCHLOROTHIAZIDE;LOSARTAN POTASSIUM, PRODUCTSYNONYM: LOSARTAN/HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 21:41:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 21:41:33
Data point term sent to Coder	System	13 Aug 2020 21:40:39
User entered 'losartan/hydrochlorothiazide'	(b) (4), (b) (6)	13 Aug 2020 21:40:06

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:17:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:57:49
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 21:40:06

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:17:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:57:49
User entered 'hypertension'	(b) (4), (b) (6)	13 Aug 2020 21:40:06

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:17:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:57:49
User entered '100/25'	(b) (4), (b) (6)	13 Aug 2020 21:40:06

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:17:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:57:49
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Aug 2020 21:40:06

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:17:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:57:49
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 21:40:06

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:17:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:57:49
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Aug 2020 21:40:06

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:17:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:57:49
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 21:40:06

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:17:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:57:49
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Aug 2020 21:40:06

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:17:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:57:49
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 21:40:06

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:17:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:57:49
User closed 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).	(b) (4), (b) (6)	14 Aug 2020 12:00:19
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.' answered with 'ongoing at enrollment' (Site from System).	(b) (4), (b) (6)	13 Aug 2020 21:40:13
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 21:40:06
User entered 'un UNK 2010'	(b) (4), (b) (6)	13 Aug 2020 21:40:06

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:57:49
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 21:40:06

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:17:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:57:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 21:40:06

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:17:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:57:49
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 21:40:06

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:17:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:57:49
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 21:40:06

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:17:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 21:40:06

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:17:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 21:40:06

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:17:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 21:40:06

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:17:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:00
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:57:49
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 17:22:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 17:22:15
Data point term sent to Coder	System	06 Oct 2020 17:21:48
User entered 'influenza Vaccine'	(b) (4), (b) (6)	06 Oct 2020 17:21:15

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:17:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:00
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:57:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 17:21:15

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:17:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:00
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:57:49
User entered 'prophylaxis'	(b) (4), (b) (6)	06 Oct 2020 17:21:15

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:17:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:00
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:57:49
User entered '.5'	(b) (4), (b) (6)	06 Oct 2020 17:21:15

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:17:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:00
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:57:49
User entered 'mL (mL)'	(b) (4), (b) (6)	06 Oct 2020 17:21:15

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:17:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:00
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:57:49
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 17:21:15

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:17:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:00
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:57:49
User entered 'once (ONCE)'	(b) (4), (b) (6)	06 Oct 2020 17:21:15

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:17:16

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:00
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:57:49
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 17:21:15

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:17:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:00
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:57:49
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	06 Oct 2020 17:21:15

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:17:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:00
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:57:49
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 17:21:15

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:17:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:00
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:57:49
User entered '05 Oct 2020'	(b) (4), (b) (6)	06 Oct 2020 17:21:15

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:00
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:57:49
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 17:21:15

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:17:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:00
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:57:49
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 17:21:15

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:17:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:00
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:57:49
User entered '05 Oct 2020'	(b) (4), (b) (6)	06 Oct 2020 17:21:15

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:17:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:00
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:57:49
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 17:21:15

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:17:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:00
User entered empty.	System	06 Oct 2020 17:21:15

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:17:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:00
User entered empty.	System	06 Oct 2020 17:21:15

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:17:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:00
User entered empty.	System	06 Oct 2020 17:21:15

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:17:16

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:04
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
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)	19 Nov 2020 22:58:06
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 22:58:06
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:57:49
Data point term sent to Coder	System	13 Nov 2020 16:03:43
User entered 'Flonase'	Crystal Rowell (b) (4)	13 Nov 2020 16:03:42

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:17:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:04
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:57:49
User entered 'No (N)'	Crystal Rowell (b) (4)	13 Nov 2020 16:03:42

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:17:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:04
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:57:49
User entered 'SARS COV-2 positive'	Crystal Rowell (b) (4)	13 Nov 2020 16:03:42

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:17:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:04
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:57:49
User entered '50'	Crystal Rowell (b) (4)	13 Nov 2020 16:03:42

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:17:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:04
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:57:49
User entered 'ug (ug)'	Crystal Rowell (b) (4)	13 Nov 2020 16:03:42

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:17:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:04
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:57:49
User entered empty.	Crystal Rowell (b) (4)	13 Nov 2020 16:03:42

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:17:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:04
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:57:49
User entered 'once daily (QD)'	Crystal Rowell (b) (4)	13 Nov 2020 16:03:42

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:17:16

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:04
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:57:49
User entered empty.	Crystal Rowell (b) (4)	13 Nov 2020 16:03:42

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:17:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:04
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:57:49
User entered 'Nasal (NASAL)'	Crystal Rowell (b) (4)	13 Nov 2020 16:03:42

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:17:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:04
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:57:49
User entered empty.	Crystal Rowell (b) (4)	13 Nov 2020 16:03:42

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:17:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:04
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:57:49
User entered '8 Nov 2020'	Crystal Rowell (b) (4)	13 Nov 2020 16:03:42

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:04
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:57:49
User entered '0'	Crystal Rowell (b) (4)	13 Nov 2020 16:03:42

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:17:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:04
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:57:49
User entered 'No (N)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	13 Nov 2020 20:25:17
User entered 'Yes (Y)'	(b) (4)	
	Crystal Rowell (b) (4)	13 Nov 2020 16:03:42
	(b) (4)	

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:17:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:04
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:57:49
User entered '8 Nov 2020' reason for change: Data Entry Error	Crystal Rowell (b) (4)	13 Nov 2020 20:25:17
User entered empty.	Crystal Rowell (b) (4)	13 Nov 2020 16:03:42

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:17:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:04
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:57:49
User entered 'No (N)'	Crystal Rowell (b) (4)	13 Nov 2020 16:03:42

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:17:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:04
User entered '1'	System	13 Nov 2020 16:03:42

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:17:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:04
User entered '1'	System	13 Nov 2020 16:03:42

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:17:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:04
User entered '804 (804)'	System	13 Nov 2020 16:03:42

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:17:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	23 Nov 2020 20:14:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 20:14:05
Data point term sent to Coder	System	23 Nov 2020 18:39:00
User entered 'benadryl'	(b) (4), (b) (6)	23 Nov 2020 18:38:49

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:17:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:38:49

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:17:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
User entered 'seasonal allergies'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:38:49

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:17:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
User entered '12.5'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:38:49

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:17:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:38:49

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:17:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:38:49

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:17:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
User entered 'as needed (PRN)' reason for change:	(b) (4)	
Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 18:47:49
User entered 'four times daily (QID)'	(b) (4), (b) (6)	23 Nov 2020 18:38:49

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:17:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:38:49

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:17:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:38:49

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:17:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:38:49

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:17:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
User entered 'un UNK 2005'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:38:49

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:38:49

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:17:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:38:49

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:17:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:38:49

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:17:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:38:49

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:17:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 18:47:49
User entered '4'	System	23 Nov 2020 18:38:49

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:17:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 18:47:49
User entered '1'	System	23 Nov 2020 18:38:49

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:17:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 18:47:49
User entered '804 (804)'	System	23 Nov 2020 18:38:49

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:17:16

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFALOXIN, PRODUCTSYNONYM: CEFALOXIN [CEFALOXIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Mar 2021 07:45:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Mar 2021 07:45:58
Data point term sent to Coder	System	26 Mar 2021 16:15:22
Coding entries removed.	(b) (4), (b) (6)	26 Mar 2021 16:15:11
User entered 'cephalexin' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Mar 2021 16:15:11
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: CIPROFLOXACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Mar 2021 09:09:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Mar 2021 09:09:33
Data point term sent to Coder	System	22 Mar 2021 16:03:51
Data point term sent to Coder	System	22 Mar 2021 16:00:47
User entered 'Ciprofloxin'	Alexandra Caillouet (b) (4)	22 Mar 2021 16:00:36

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:17:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:42:29
	(b) (4)	
Signature has been broken.	Amy Thomassie (b) (4)	09 Apr 2021 14:50:39
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Amy Thomassie (b) (4)	09 Apr 2021 14:50:39
	(b) (4)	
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
	(b) (4)	
User entered 'No (N)'	Alexandra Caillouet	22 Mar 2021 16:00:36
	(b) (4)	

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:17:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
	(b) (4)	
User entered 'Complete AV heart block/PACEMAKER PLACEMENT' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	22 Mar 2021 16:03:27
User entered 'Pacemaker Placement'	Alexandra Caillouet (b) (4)	22 Mar 2021 16:00:36

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:17:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
	(b) (4)	
User entered '500'	Alexandra Caillouet	22 Mar 2021 16:00:36
	(b) (4)	

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:17:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
	(b) (4)	
User entered 'mg (mg)'	Alexandra Caillouet	22 Mar 2021 16:00:36
	(b) (4)	

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:17:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
	(b) (4)	
User entered empty.	Alexandra Caillouet	22 Mar 2021 16:00:36
	(b) (4)	

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:17:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
	(b) (4)	
User entered 'three times daily (TID)'	Alexandra Caillouet	22 Mar 2021 16:00:36
	(b) (4)	

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:17:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
	(b) (4)	
User entered empty.	Alexandra Caillouet	22 Mar 2021 16:00:36
	(b) (4)	

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:17:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
	(b) (4)	
User entered 'Oral (ORAL)'	Alexandra Caillouet	22 Mar 2021 16:00:36
	(b) (4)	

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:17:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
	(b) (4)	
User entered empty.	Alexandra Caillouet	22 Mar 2021 16:00:36
	(b) (4)	

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:17:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
	(b) (4)	
User entered '20 Mar 2021'	Alexandra Caillouet	22 Mar 2021 16:00:36
	(b) (4)	

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
	(b) (4)	
User entered '0'	Alexandra Caillouet	22 Mar 2021 16:00:36
	(b) (4)	

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:17:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:42:29
	(b) (4)	
Signature has been broken.	Amy Thomassie (b) (4)	09 Apr 2021 14:50:39
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Amy Thomassie (b) (4)	09 Apr 2021 14:50:39
	(b) (4)	
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
	(b) (4)	
User entered 'Yes (Y)'	Alexandra Caillouet	22 Mar 2021 16:00:36
	(b) (4)	

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:17:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:42:29
	(b) (4)	
Signature has been broken.	Amy Thomassie (b) (4)	09 Apr 2021 14:50:39
	(b) (4)	
User entered '27 Mar 2021' reason for change: Data Entry Error	Amy Thomassie (b) (4)	09 Apr 2021 14:50:39
	(b) (4)	
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
	(b) (4)	
User entered empty.	Alexandra Caillouet	22 Mar 2021 16:00:36
	(b) (4)	

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:17:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
	(b) (4)	
User entered 'No (N)'	Alexandra Caillouet	22 Mar 2021 16:00:36
	(b) (4)	

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:17:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	22 Mar 2021 16:00:36

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:17:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Mar 2021 16:00:36

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:17:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Mar 2021 16:00:36

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:17:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: NORCO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Mar 2021 06:33:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Mar 2021 06:33:04
Data point term sent to Coder	System	26 Mar 2021 16:21:29
Coding entries removed.	(b) (4), (b) (6)	26 Mar 2021 16:21:04
User entered 'NORCO Hydrocodone/acetaminophen' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Mar 2021 16:21:04
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: NORCO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Mar 2021 16:18:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Mar 2021 16:18:26
Data point term sent to Coder	System	26 Mar 2021 16:17:23
User entered 'NORCO'	(b) (4), (b) (6)	26 Mar 2021 16:17:03

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:17:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 16:17:03

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:17:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
User entered 'post-op Pacemaker placement'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 16:17:03

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:17:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
User entered '5/325'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 16:17:03

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:17:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 16:17:03

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:17:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 16:17:03

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:17:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 16:17:03

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:17:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 16:17:03

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:17:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 16:17:03

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:17:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 16:17:03

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:17:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
User entered '20 Mar 2021'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 16:17:03

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 16:17:03

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:17:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 16:17:03

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:17:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 16:17:03

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:17:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 16:17:03

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:17:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Mar 2021 16:17:03

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:17:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Mar 2021 16:17:03

US3362125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:17:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Mar 2021 16:17:03

US3362125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:17:16

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:00:22
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
DataPoint Un-verified.	(b) (4)	22 Mar 2021 16:01:28
User entered 'Yes (Y)' reason for change: Data Entry Error	Alexandra Caillouet	22 Mar 2021 16:01:28
DataPoint Verified.	(b) (4)	19 Nov 2020 18:58:01
User entered 'No (N)'	(b) (4), (b) (6)	29 Aug 2020 13:32:31

US3362125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:17:16

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
	(b) (4)	
User entered '18 Mar 2021'	Alexandra Caillouet	22 Mar 2021 16:02:14
	(b) (4)	

US3362125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:17:16

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
User entered 'Dual Chamber Pacemaker Placement'	(b) (4) Alexandra Caillouet (b) (4)	22 Mar 2021 16:02:14

US3362125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:17:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	(b) (4) System	22 Mar 2021 16:02:31
User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	22 Mar 2021 16:02:14
User entered 'Adverse Event (AE)'	Alexandra Caillouet (b) (4)	22 Mar 2021 16:02:14

US3362125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:17:16

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:40
	(b) (4)	
User entered empty; reason for change Data Entry Error	Alexandra Caillouet	22 Mar 2021 16:02:31
	(b) (4)	
User entered 'Complete AV heart Block'	Alexandra Caillouet	22 Mar 2021 16:02:14
	(b) (4)	

US3362125

Folder: SAE USA-US112-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:55:44
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:55:36
User entered		
'USA-US112-2020-MRNA-1273-P301000010'	System	16 Nov 2020 16:55:14

US3362125

Folder: SAE USA-US112-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:26:44
User entered 'No (N)'	System	19 Mar 2021 18:19:11
Un-reviewed for Safety.	System	19 Mar 2021 18:13:17
DataPoint Un-verified.	System	19 Mar 2021 18:13:17
User entered 'Yes (Y)'	System	19 Mar 2021 18:13:17
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:55:44
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:55:36
User entered 'No (N)'	System	16 Nov 2020 16:55:14

US3362125

Folder: SAE USA-US112-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:55:44
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:55:36
User entered 'No (N)'	System	16 Nov 2020 16:55:14

US3362125

Folder: SAE USA-US112-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:55:44
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:55:36
User entered 'No (N)'	System	16 Nov 2020 16:55:14

US3362125

Folder: SAE USA-US112-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:26:44
User entered 'No (N)'	System	19 Mar 2021 18:19:11
Un-reviewed for Safety.	System	19 Mar 2021 18:13:17
DataPoint Un-verified.	System	19 Mar 2021 18:13:17
User entered 'Yes (Y)'	System	19 Mar 2021 18:13:17
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:55:44
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:55:36
User entered 'No (N)'	System	16 Nov 2020 16:55:14

US3362125

Folder: SAE USA-US112-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:55:44
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:55:36
User entered 'No (N)'	System	16 Nov 2020 16:55:14

US3362125

Folder: SAE USA-US112-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:55:44
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:55:36
User entered 'No (N)'	System	16 Nov 2020 16:55:14

US3362125

Folder: SAE USA-US112-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:55:44
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:55:36
User entered 'No (N)'	System	16 Nov 2020 16:55:14

US3362125

Folder: SAE USA-US112-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:55:44
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:55:36
User entered 'Jordan'	System	16 Nov 2020 16:55:14

US3362125

Folder: SAE USA-US112-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:55:44
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:55:36
User entered 'Whatley'	System	16 Nov 2020 16:55:14

US3362125

Folder: SAE USA-US112-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:55:44
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:55:36
User entered '5326 O'donovan dr'	System	16 Nov 2020 16:55:14

US3362125

Folder: SAE USA-US112-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:55:44
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:55:36
User entered 'baton rouge'	System	16 Nov 2020 16:55:14

US3362125

Folder: SAE USA-US112-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:55:44
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:55:36
User entered '70808'	System	16 Nov 2020 16:55:14

US3362125

Folder: SAE USA-US112-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:28:30
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:55:44
User entered 'US'	System	16 Nov 2020 16:55:46

US3362125

Folder: SAE USA-US112-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	30 Nov 2020 18:28:42
User entered '1'	System	16 Nov 2020 16:55:46

US3362125

Folder: SAE USA-US112-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:55:44
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:55:36
User entered		
'USA-US112-2020-MRNA-1273-P301000010'	System	16 Nov 2020 16:55:14

US3362125

Folder: SAE USA-US112-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:26:44
User entered 'No (N)'	System	19 Mar 2021 18:19:11
Un-reviewed for Safety.	System	19 Mar 2021 18:13:17
DataPoint Un-verified.	System	19 Mar 2021 18:13:17
User entered 'Yes (Y)'	System	19 Mar 2021 18:13:17
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:55:44
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:55:36
User entered 'No (N)'	System	16 Nov 2020 16:55:14

US3362125

Folder: SAE USA-US112-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:55:44
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:55:36
User entered 'No (N)'	System	16 Nov 2020 16:55:14

US3362125

Folder: SAE USA-US112-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:55:44
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:55:36
User entered 'No (N)'	System	16 Nov 2020 16:55:14

US3362125

Folder: SAE USA-US112-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:26:44
User entered 'No (N)'	System	19 Mar 2021 18:19:11
Un-reviewed for Safety.	System	19 Mar 2021 18:13:17
DataPoint Un-verified.	System	19 Mar 2021 18:13:17
User entered 'Yes (Y)'	System	19 Mar 2021 18:13:17
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:55:44
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:55:36
User entered 'No (N)'	System	16 Nov 2020 16:55:14

US3362125

Folder: SAE USA-US112-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:55:44
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:55:36
User entered 'No (N)'	System	16 Nov 2020 16:55:14

US3362125

Folder: SAE USA-US112-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:55:44
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:55:36
User entered 'No (N)'	System	16 Nov 2020 16:55:14

US3362125

Folder: SAE USA-US112-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:55:44
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:55:36
User entered 'No (N)'	System	16 Nov 2020 16:55:14

US3362125

Folder: SAE USA-US112-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:55:44
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:55:36
User entered 'Jordan'	System	16 Nov 2020 16:55:14

US3362125

Folder: SAE USA-US112-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:55:44
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:55:36
User entered 'Whatley'	System	16 Nov 2020 16:55:14

US3362125

Folder: SAE USA-US112-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:55:44
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:55:36
User entered '5326 O'donovan dr'	System	16 Nov 2020 16:55:14

US3362125

Folder: SAE USA-US112-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:55:44
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:55:36
User entered 'baton rouge'	System	16 Nov 2020 16:55:14

US3362125

Folder: SAE USA-US112-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:55:44
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:55:36
User entered '70808'	System	16 Nov 2020 16:55:14

US3362125

Folder: SAE USA-US112-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:28:30
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:55:44
User entered 'US'	System	16 Nov 2020 16:55:46

US3362125

Folder: SAE USA-US112-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	30 Nov 2020 18:28:42
User entered '1'	System	16 Nov 2020 16:55:46

US3362125

Folder: SAE USA-US112-2020-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:17:16

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:55:44
User entered '16/Nov/2020 11:55'	System	16 Nov 2020 16:55:46

US3362125

Folder: SAE USA-US112-2020-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:17:16

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.

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:28:30
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:55:44
User entered 'I'	(b) (4), (b) (6)	16 Nov 2020 16:55:46

US3362125

Folder: SAE USA-US112-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:55:44
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:55:36
User entered		
'USA-US112-2020-MRNA-1273-P301000010'	System	16 Nov 2020 16:55:14

US3362125

Folder: SAE USA-US112-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:26:44
User entered 'No (N)'	System	19 Mar 2021 18:19:11
Un-reviewed for Safety.	System	19 Mar 2021 18:13:17
DataPoint Un-verified.	System	19 Mar 2021 18:13:17
User entered 'Yes (Y)'	System	19 Mar 2021 18:13:17
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:55:44
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:55:36
User entered 'No (N)'	System	16 Nov 2020 16:55:14

US3362125

Folder: SAE USA-US112-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:55:44
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:55:36
User entered 'No (N)'	System	16 Nov 2020 16:55:14

US3362125

Folder: SAE USA-US112-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:55:44
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:55:36
User entered 'No (N)'	System	16 Nov 2020 16:55:14

US3362125

Folder: SAE USA-US112-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:26:44
User entered 'No (N)'	System	19 Mar 2021 18:19:11
Un-reviewed for Safety.	System	19 Mar 2021 18:13:17
DataPoint Un-verified.	System	19 Mar 2021 18:13:17
User entered 'Yes (Y)'	System	19 Mar 2021 18:13:17
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:55:44
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:55:36
User entered 'No (N)'	System	16 Nov 2020 16:55:14

US3362125

Folder: SAE USA-US112-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:55:44
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:55:36
User entered 'No (N)'	System	16 Nov 2020 16:55:14

US3362125

Folder: SAE USA-US112-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:55:44
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:55:36
User entered 'No (N)'	System	16 Nov 2020 16:55:14

US3362125

Folder: SAE USA-US112-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:55:44
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:55:36
User entered 'No (N)'	System	16 Nov 2020 16:55:14

US3362125

Folder: SAE USA-US112-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:55:44
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:55:36
User entered 'Jordan'	System	16 Nov 2020 16:55:14

US3362125

Folder: SAE USA-US112-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:55:44
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:55:36
User entered 'Whatley'	System	16 Nov 2020 16:55:14

US3362125

Folder: SAE USA-US112-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:55:44
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:55:36
User entered '5326 O'donovan dr'	System	16 Nov 2020 16:55:14

US3362125

Folder: SAE USA-US112-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:55:44
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:55:36
User entered 'baton rouge'	System	16 Nov 2020 16:55:14

US3362125

Folder: SAE USA-US112-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:55:44
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:55:36
User entered '70808'	System	16 Nov 2020 16:55:14

US3362125

Folder: SAE USA-US112-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:28:30
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:55:44
User entered 'US'	System	16 Nov 2020 16:55:46

US3362125

Folder: SAE USA-US112-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	30 Nov 2020 18:28:42
User entered '1'	System	16 Nov 2020 16:55:46

US3362125

Folder: SAE USA-US112-2020-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:17:16

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:26:44
User entered '30/Nov/2020 18:28'	System	30 Nov 2020 18:28:42

US3362125

Folder: SAE USA-US112-2020-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:17:16

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.

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:26:44
User entered 'I'	(b) (4), (b) (6)	30 Nov 2020 18:28:42

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	12 Apr 2021 19:27:02
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 18:20:11
User entered 'USA-US112-2021-MRNA-1273-P301000015'	System	19 Mar 2021 18:19:11

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:27:02
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 18:20:11
User entered 'Yes (Y)'	System	19 Mar 2021 18:19:11

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:27:02
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 18:20:11
User entered 'No (N)'	System	19 Mar 2021 18:19:11

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:27:02
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 18:20:11
User entered 'No (N)'	System	19 Mar 2021 18:19:11

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:27:02
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 18:20:11
User entered 'Yes (Y)'	System	19 Mar 2021 18:19:11

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:27:02
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 18:20:11
User entered 'No (N)'	System	19 Mar 2021 18:19:11

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:27:02
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 18:20:11
User entered 'No (N)'	System	19 Mar 2021 18:19:11

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	12 Apr 2021 19:27:02
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 18:20:11
User entered 'No (N)'	System	19 Mar 2021 18:19:11

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:27:02
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 18:20:11
User entered 'Jordan'	System	19 Mar 2021 18:19:11

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:27:02
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 18:20:11
User entered 'Whatley'	System	19 Mar 2021 18:19:11

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:27:02
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 18:20:11
User entered '5326 O'donovan dr'	System	19 Mar 2021 18:19:11

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:27:02
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 18:20:11
User entered 'baton rouge'	System	19 Mar 2021 18:19:11

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:27:02
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 18:20:11
User entered '70808'	System	19 Mar 2021 18:19:11

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:27:02
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 18:20:11
User entered 'US'	System	19 Mar 2021 18:20:07

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	12 Apr 2021 14:42:05
User entered '2'	System	29 Mar 2021 13:50:08
User entered '1'	System	19 Mar 2021 18:20:07

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:27:02
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 18:20:11
User entered		
'USA-US112-2021-MRNA-1273-P301000015'	System	19 Mar 2021 18:19:11

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:27:02
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 18:20:11
User entered 'Yes (Y)'	System	19 Mar 2021 18:19:11

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:27:02
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 18:20:11
User entered 'No (N)'	System	19 Mar 2021 18:19:11

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:27:02
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 18:20:11
User entered 'No (N)'	System	19 Mar 2021 18:19:11

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:27:02
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 18:20:11
User entered 'Yes (Y)'	System	19 Mar 2021 18:19:11

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:27:02
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 18:20:11
User entered 'No (N)'	System	19 Mar 2021 18:19:11

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:27:02
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 18:20:11
User entered 'No (N)'	System	19 Mar 2021 18:19:11

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:27:02
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 18:20:11
User entered 'No (N)'	System	19 Mar 2021 18:19:11

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:27:02
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 18:20:11
User entered 'Jordan'	System	19 Mar 2021 18:19:11

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:27:02
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 18:20:11
User entered 'Whatley'	System	19 Mar 2021 18:19:11

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:27:02
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 18:20:11
User entered '5326 O'donovan dr'	System	19 Mar 2021 18:19:11

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:27:02
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 18:20:11
User entered 'baton rouge'	System	19 Mar 2021 18:19:11

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:27:02
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 18:20:11
User entered '70808'	System	19 Mar 2021 18:19:11

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:27:02
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 18:20:11
User entered 'US'	System	19 Mar 2021 18:20:07

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	12 Apr 2021 14:42:05
User entered '2'	System	29 Mar 2021 13:50:08
User entered '1'	System	19 Mar 2021 18:20:07

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:17:16

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:27:02
User entered '19/Mar/2021 14:20'	System	19 Mar 2021 18:20:07

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:17:16

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.

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:27:02
Reviewed for Safety.		19 Mar 2021 18:20:11
User entered '1'		19 Mar 2021 18:20:07

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	12 Apr 2021 19:27:02
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 18:20:11
User entered 'USA-US112-2021-MRNA-1273-P301000015'	System	19 Mar 2021 18:19:11

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:27:02
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 18:20:11
User entered 'Yes (Y)'	System	19 Mar 2021 18:19:11

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:27:02
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 18:20:11
User entered 'No (N)'	System	19 Mar 2021 18:19:11

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:27:02
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 18:20:11
User entered 'No (N)'	System	19 Mar 2021 18:19:11

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:27:02
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 18:20:11
User entered 'Yes (Y)'	System	19 Mar 2021 18:19:11

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:27:02
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 18:20:11
User entered 'No (N)'	System	19 Mar 2021 18:19:11

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:27:02
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 18:20:11
User entered 'No (N)'	System	19 Mar 2021 18:19:11

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:27:02
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 18:20:11
User entered 'No (N)'	System	19 Mar 2021 18:19:11

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:27:02
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 18:20:11
User entered 'Jordan'	System	19 Mar 2021 18:19:11

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:27:02
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 18:20:11
User entered 'Whatley'	System	19 Mar 2021 18:19:11

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:27:02
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 18:20:11
User entered '5326 O'donovan dr'	System	19 Mar 2021 18:19:11

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:27:02
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 18:20:11
User entered 'baton rouge'	System	19 Mar 2021 18:19:11

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:27:02
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 18:20:11
User entered '70808'	System	19 Mar 2021 18:19:11

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:27:02
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 18:20:11
User entered 'US'	System	19 Mar 2021 18:20:07

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	12 Apr 2021 14:42:05
User entered '2'	System	29 Mar 2021 13:50:08
User entered '1'	System	19 Mar 2021 18:20:07

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:17:16

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:27:02
User entered '29/Mar/2021 09:50'	System	29 Mar 2021 13:50:08

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:17:16

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.

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:27:02
Reviewed for Safety.		12 Apr 2021 14:41:39
User entered '1'		29 Mar 2021 13:50:08

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:27:02
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 18:20:11
User entered		
'USA-US112-2021-MRNA-1273-P301000015'	System	19 Mar 2021 18:19:11

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:27:02
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 18:20:11
User entered 'Yes (Y)'	System	19 Mar 2021 18:19:11

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:27:02
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 18:20:11
User entered 'No (N)'	System	19 Mar 2021 18:19:11

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:27:02
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 18:20:11
User entered 'No (N)'	System	19 Mar 2021 18:19:11

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:27:02
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 18:20:11
User entered 'Yes (Y)'	System	19 Mar 2021 18:19:11

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:27:02
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 18:20:11
User entered 'No (N)'	System	19 Mar 2021 18:19:11

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:27:02
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 18:20:11
User entered 'No (N)'	System	19 Mar 2021 18:19:11

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:27:02
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 18:20:11
User entered 'No (N)'	System	19 Mar 2021 18:19:11

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:27:02
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 18:20:11
User entered 'Jordan'	System	19 Mar 2021 18:19:11

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:27:02
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 18:20:11
User entered 'Whatley'	System	19 Mar 2021 18:19:11

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:27:02
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 18:20:11
User entered '5326 O'donovan dr'	System	19 Mar 2021 18:19:11

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:27:02
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 18:20:11
User entered 'baton rouge'	System	19 Mar 2021 18:19:11

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:27:02
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 18:20:11
User entered '70808'	System	19 Mar 2021 18:19:11

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:27:02
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 18:20:11
User entered 'US'	System	19 Mar 2021 18:20:07

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	12 Apr 2021 14:42:05
User entered '2'	System	29 Mar 2021 13:50:08
User entered '1'	System	19 Mar 2021 18:20:07

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:17:16

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:27:02
User entered '12/Apr/2021 10:41'	System	12 Apr 2021 14:42:05

US3362125

Folder: SAE USA-US112-2021-MRNA-1273-P301000015

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:17:16

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.

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:17:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:27:02
User entered 'I'	(b) (4), (b) (6)	12 Apr 2021 14:42:05