

US3462244 (Prod: Crisor, LLC)

Generated By: KC Joubran

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All time stamps listed in this document are displayed in GMT

US3462244

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 20:17:49

Generated On: 09 Jun 2021 17:44:05

[Participant ID](#)

US3462244

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

US3462244

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:39:51

Generated On: 09 Jun 2021 17:44:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 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) 13 Feb 2021 01:39:50

Generated On: 09 Jun 2021 17:44:05

Date of Birth (MMM yyyy)	(b) (6) 1993
Age	27
Age Units	YEARS
Age (Derived)	27
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 01:39:50

Generated On: 09 Jun 2021 17:44:05

Date of Informed Consent (<i>dd MMM yyyy</i>)	19 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) 13 Feb 2021 01:39:50

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 01:39:50

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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) 13 Feb 2021 01:39:50

Generated On: 09 Jun 2021 17:44:05

Condition	SEASONAL ALLERGIC RHINITIS
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 13 Feb 2021 01:39:50

Generated On: 09 Jun 2021 17:44:05

Condition	RAYNAUD SYNDROME
Start date (dd MMM yyyy)	UN UNK 2011
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 2011
Start Year (derived)	2011
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 13 Feb 2021 01:39:50

Generated On: 09 Jun 2021 17:44:05

Condition	ANXIETY
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 (4)

Data signed: (b) (4) 13 Feb 2021 01:39:50

Generated On: 09 Jun 2021 17:44:05

Condition	DRUG ALLERGY TO SULFA MEDICATIONS
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 (5)

Data signed: (b) (4) 13 Feb 2021 01:39:50

Generated On: 09 Jun 2021 17:44:05

Condition	HSV-1
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 (6)

Data signed: (b) (4) 13 Feb 2021 01:39:50

Generated On: 09 Jun 2021 17:44:05

Condition	DEPRESSION
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: Vital Signs

Data signed: (b) (4) 13 Feb 2021 01:39:51

Generated On: 09 Jun 2021 17:44:05

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	19 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	10:44 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 10:44
Height (<i>xxx.x</i>)	158 cm
Weight (<i>xxx.x</i>)	45 kg
BMI (<i>xxx.x</i>)	18.02596 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:39:50

Generated On: 09 Jun 2021 17:44:05

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 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: Screening

Form: Childbearing Potential

Data signed: (b) (4) 13 Feb 2021 01:39:50

Generated On: 09 Jun 2021 17:44:05

Date of assessment (*dd MMM yyyy*) 19 AUG 2020

Is the participant of childbearing potential? Yes ☒
No ☐

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) _____

Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 13 Feb 2021 01:39:50

Generated On: 09 Jun 2021 17:44:05

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	19 AUG 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 01:39:50

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 01:39:50

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:39:51

Generated On: 09 Jun 2021 17:44:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 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) 13 Feb 2021 01:39:51

Generated On: 09 Jun 2021 17:44:05

What was the date of randomization? (dd MMM yyyy) 19 AUG 2020

What was the participant's randomization number? 105915

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 01:39:51

Generated On: 09 Jun 2021 17:44:05

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 01:39:51

Generated On: 09 Jun 2021 17:44:05

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)	19 AUG 2020
Time of assessment (00:00-23:59)	10:44 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 10:44
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	94 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 01:39:51

Generated On: 09 Jun 2021 17:44:05

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)	19 AUG 2020
Time of assessment (00:00-23:59)	11:52 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 11:52
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:39:51

Generated On: 09 Jun 2021 17:44:05

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 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: Pregnancy Test

Data signed: (b) (4) 13 Feb 2021 01:39:51

Generated On: 09 Jun 2021 17:44:05

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☒

Collection date _____

Collection time _____

Collection date and time (derived) _____

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 01:39:51

Generated On: 09 Jun 2021 17:44:05

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) 19 AUG 2020

What was the treatment time? (00:00-23:59) 11:21 (24 HR)

Treatment Date and Time (derived) 19 AUG 2020 11:21

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 01:39:51

Generated On: 09 Jun 2021 17:44:05

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 AUG 2020
Collection time (00:00-23:59)	11:14 (24 HR)
Collection date and time (derived)	19 AUG 2020 11:14

US3462244

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 01:39:51

Generated On: 09 Jun 2021 17:44:05

Collection date (dd MMM yyyy)			19 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:17	19 AUG 2020 11:17
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:39:51

Generated On: 09 Jun 2021 17:44:05

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 17:44:05

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 AUG 2020 11:54

PC Open Date & Time

19 AUG 2020 11:41

PC Close Date & Time

19 AUG 2020 14:11

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

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 98.8 °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):

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 19 AUG 2020 22:06

PC Open Date & Time 19 AUG 2020 15:06

PC Close Date & Time 20 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:44:05

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

99.1 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

20 AUG 2020 22:29

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:44:05

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

99.2 °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

21 AUG 2020 23:59

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:44:05

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

98.7 °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

22 AUG 2020 22:41

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:44:05

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

98.7 °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

24 AUG 2020 00:00

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:44:05

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

98.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 00:00

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:44:05

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

99.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 21:47

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:44:05

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

19 AUG 2020 11:53

PC Open Date & Time

19 AUG 2020 11:41

PC Close Date & Time

19 AUG 2020 14:11

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

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

19 AUG 2020 22:07

PC Open Date & Time

19 AUG 2020 15:06

PC Close Date & Time

20 AUG 2020 11:59

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:44:05

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

20 AUG 2020 22:30

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:44:05

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

21 AUG 2020 23:59

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT	DAY 4
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	22 AUG 2020 22:42
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:44:05

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

24 AUG 2020 00:00

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:44:05

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

25 AUG 2020 00:01

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:44:05

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

25 AUG 2020 21:46

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:44:05

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 ☐

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:44:05

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

No ☒

Yes ☐

PC Time stamp	19 AUG 2020 11:54
PC Open Date & Time	19 AUG 2020 11:41
PC Close Date & Time	19 AUG 2020 14:11

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

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 ☐

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

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

No ☒

Yes ☐

PC Time stamp	19 AUG 2020 22:08
PC Open Date & Time	19 AUG 2020 15:06
PC Close Date & Time	20 AUG 2020 11:59

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:44:05

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

50 of 2707

EAB) (1725)

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:44:05

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 22:31
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:44:05

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

52 of 2707

EAB) (1725)

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:44:05

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 23:59
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:44:05

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

54 of 2707

EAB) (1725)

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:44:05

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 22:43
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:44:05

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

56 of 2707

EAB) (1725)

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:44:05

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 00:01
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:44:05

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 ☒

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:44:05

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 00:01
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

60 of 2707

EAB) (1725)

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:44:05

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 21:47
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3462244

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:39:50

Generated On: 09 Jun 2021 17:44:05

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 26 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3462244

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:39:50

Generated On: 09 Jun 2021 17:44:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462244

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:39:50

Generated On: 09 Jun 2021 17:44:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462244

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:39:50

Generated On: 09 Jun 2021 17:44:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462244

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:39:50

Generated On: 09 Jun 2021 17:44:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462244

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:39:50

Generated On: 09 Jun 2021 17:44:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462244

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:40:11

Generated On: 09 Jun 2021 17:44:05

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

US3462244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 01:40:11

Generated On: 09 Jun 2021 17:44:05

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)	16 SEP 2020
Time of assessment (00:00-23:59)	11:18 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 11:18
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	97 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	56 mmHg
Diastolic Blood Pressure units	MMHG

US3462244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 01:40:11

Generated On: 09 Jun 2021 17:44:05

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)	16 SEP 2020
Time of assessment (00:00-23:59)	12:21 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 12:21
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input checked="" type="checkbox"/>
If Other, specify	TYMPANIC
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 mmHg
Diastolic Blood Pressure units	MMHG

US3462244

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:40:11

Generated On: 09 Jun 2021 17:44:05

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.

US3462244

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 13 Feb 2021 01:40:11

Generated On: 09 Jun 2021 17:44:05

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	16 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3462244

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 01:39:51

Generated On: 09 Jun 2021 17:44:05

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) 16 SEP 2020

What was the treatment time? (00:00-23:59) 11:50 (24 HR)

Treatment Date and Time (derived) 16 SEP 2020 11:50

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

US3462244

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 01:39:51

Generated On: 09 Jun 2021 17:44:05

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

16 SEP 2020

Collection time (00:00-23:59)

11:34 (24 HR)

Collection date and time (derived)

16 SEP 2020 11:34

US3462244

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 01:39:51

Generated On: 09 Jun 2021 17:44:05

Collection date (dd MMM yyyy)			16 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:36	16 SEP 2020 11:36
Nasopharyngeal Swab 2	No		

US3462244

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:39:51

Generated On: 09 Jun 2021 17:44:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:44:05

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

16 SEP 2020 12:20

PC Open Date & Time

16 SEP 2020 12:10

PC Close Date & Time

16 SEP 2020 14:40

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

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 99.3 °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):

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 16 SEP 2020 20:58

PC Open Date & Time 16 SEP 2020 15:35

PC Close Date & Time 17 SEP 2020 11:59

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.3 °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):

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 17 SEP 2020 22:33

PC Open Date & Time 17 SEP 2020 12:00

PC Close Date & Time 18 SEP 2020 11:59

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:44:05

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

18 SEP 2020 22:04

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:44:05

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

99.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 22:27

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:44:05

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

98.8 °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

20 SEP 2020 22:21

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:44:05

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

99.1 °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 23:15

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

22 SEP 2020 23:21

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:44:05

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

16 SEP 2020 12:21

PC Open Date & Time

16 SEP 2020 12:10

PC Close Date & Time

16 SEP 2020 14:40

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

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

16 SEP 2020 21:00

PC Open Date & Time

16 SEP 2020 15:35

PC Close Date & Time

17 SEP 2020 11:59

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:44:05

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

17 SEP 2020 22:34

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:44:05

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

18 SEP 2020 21:54

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:44:05

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

19 SEP 2020 22:27

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:44:05

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

20 SEP 2020 22:22

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:44:05

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

21 SEP 2020 23:16

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:44:05

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

22 SEP 2020 23:17

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:44:05

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 ☐

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:44:05

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

No ☒

Yes ☐

PC Time stamp	16 SEP 2020 12:21
PC Open Date & Time	16 SEP 2020 12:10
PC Close Date & Time	16 SEP 2020 14:40

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

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 ☐

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

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

No ☒

Yes ☐

PC Time stamp	16 SEP 2020 21:02
PC Open Date & Time	16 SEP 2020 15:35
PC Close Date & Time	17 SEP 2020 11:59

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:44:05

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 ☒

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EAB) (1725)

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:44:05

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 22:35
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:44:05

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)

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:44:05

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 21:53
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:44:05

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 22:28
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:44:05

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 ☒

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EAB) (1725)

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:44:05

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 22:23
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:44:05

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 ☒

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:44:05

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 23:16
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:44:05

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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Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:44:05

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 23:21
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3462244

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:39:50

Generated On: 09 Jun 2021 17:44:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462244

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:39:50

Generated On: 09 Jun 2021 17:44:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462244

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:39:50

Generated On: 09 Jun 2021 17:44:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462244

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:39:50

Generated On: 09 Jun 2021 17:44:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462244

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:39:50

Generated On: 09 Jun 2021 17:44:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462244

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:39:50

Generated On: 09 Jun 2021 17:44:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462244

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:40:12

Generated On: 09 Jun 2021 17:44:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 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

US3462244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 01:40:12

Generated On: 09 Jun 2021 17:44:05

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) _____

US3462244

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:40:12

Generated On: 09 Jun 2021 17:44:05

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.

US3462244

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 01:40:12

Generated On: 09 Jun 2021 17:44:05

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 OCT 2020

Collection time (00:00-23:59)

11:26 (24 HR)

Collection date and time (derived)

14 OCT 2020 11:26

US3462244

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:40:12

Generated On: 09 Jun 2021 17:44:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 OCT 2020 20:03:16

Patient Cloud Open Date & Time

19 OCT 2020 00:01

Patient Cloud Close Date & Time

23 OCT 2020 23:59

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	False
Chills	False
Cough	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	False
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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	30 OCT 2020 16:30:12
Patient Cloud Open Date & Time	26 OCT 2020 00:01
Patient Cloud Close Date & Time	30 OCT 2020 23:59

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	06 NOV 2020 18:18:00
Patient Cloud Open Date & Time	02 NOV 2020 00:01
Patient Cloud Close Date & Time	06 NOV 2020 23:59

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 NOV 2020 17:37:32
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

27 NOV 2020 17:30:46

Patient Cloud Open Date & Time

27 NOV 2020 00:01

Patient Cloud Close Date & Time

01 DEC 2020 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	False
Chills	False
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	True
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	04 DEC 2020 13:43:58
Patient Cloud Open Date & Time	04 DEC 2020 00:01
Patient Cloud Close Date & Time	08 DEC 2020 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

11 DEC 2020 20:35:09

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

[Patient Cloud Close Date & Time](#)

22 DEC 2020 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2020 00:01
Patient Cloud Close Date & Time	29 DEC 2020 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

01 JAN 2021 12:44:50

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

08 JAN 2021 12:21:49

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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 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"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 JAN 2021 10:16:48
Patient Cloud Open Date & Time	22 JAN 2021 00:01
Patient Cloud Close Date & Time	26 JAN 2021 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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 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"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 JAN 2021 16:41:36
Patient Cloud Open Date & Time	29 JAN 2021 00:01
Patient Cloud Close Date & Time	02 FEB 2021 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

05 FEB 2021 15:11:53

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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 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"/>

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

[Patient Cloud Close Date & Time](#)

16 FEB 2021 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 FEB 2021 23:34:35

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 MAR 2021 23:13:11
Patient Cloud Open Date & Time	26 FEB 2021 00:01
Patient Cloud Close Date & Time	02 MAR 2021 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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	09 MAR 2021 18:49:13
Patient Cloud Open Date & Time	05 MAR 2021 00:01
Patient Cloud Close Date & Time	09 MAR 2021 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

16 MAR 2021 20:30:47

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

23 MAR 2021 18:37:13

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 MAR 2021 20:45:25

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

06 APR 2021 21:19:54

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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	13 APR 2021 20:41:59
Patient Cloud Open Date & Time	09 APR 2021 00:01
Patient Cloud Close Date & Time	13 APR 2021 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

20 APR 2021 16:01:05

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

27 APR 2021 15:56:50

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

[Patient Cloud Close Date & Time](#)

04 MAY 2021 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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 ☐

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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"/>

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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"/>

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
Patient Cloud Close Date & Time	15 JUN 2021 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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 ☐

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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 ☐

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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="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"/>

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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"/>

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2021 00:01
Patient Cloud Close Date & Time	27 JUL 2021 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

Patient Cloud Open Date & Time	13 AUG 2021 00:01
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Patient Cloud Close Date & Time	17 AUG 2021 23:59
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US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

Patient Cloud Open Date & Time	20 AUG 2021 00:01
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Patient Cloud Close Date & Time	24 AUG 2021 23:59
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US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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 ☐

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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 ☐

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
Patient Cloud Close Date & Time	28 SEP 2021 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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"/>

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

Patient Cloud Open Date & Time	15 OCT 2021 00:01
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Patient Cloud Close Date & Time	19 OCT 2021 23:59
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US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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="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"/>

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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"/>

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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 ☐

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
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Patient Cloud Close Date & Time	14 DEC 2021 23:59
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US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	21 DEC 2021 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	28 DEC 2021 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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 ☐

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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 ☐

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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 ☐

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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"/>

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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="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"/>

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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 ☐

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

[Patient Cloud Open Date & Time](#)

18 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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 ☐

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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 ☐

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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 ☐

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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 ☐

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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 ☐

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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 ☐

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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"/>

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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"/>

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 APR 2022 00:01
Patient Cloud Close Date & Time	19 APR 2022 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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"/>

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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="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"/>

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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"/>

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

DAY 656

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

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

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

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

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

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

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

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

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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 ☐

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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"/>

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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 ☐

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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"/>

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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"/>

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

[Patient Cloud Open Date & Time](#)

08 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 JUL 2022 00:01
Patient Cloud Close Date & Time	19 JUL 2022 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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"/>

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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"/>

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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="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"/>

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 AUG 2022 00:01
Patient Cloud Close Date & Time	16 AUG 2022 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

[Patient Cloud Open Date & Time](#)

19 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 AUG 2022 00:01
Patient Cloud Close Date & Time	30 AUG 2022 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

DAY 754

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

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

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

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

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

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

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 ☐

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

09 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

16 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

DAY 768

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

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

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

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

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

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

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

23 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

DAY 775

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

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

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

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

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

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

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

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

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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 ☐

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

[Patient Cloud Open Date & Time](#)

07 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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"/>

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2022 23:59

US3462244

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:44:05

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 03:43:31

US3462244

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:20:40

Generated On: 09 Jun 2021 17:44:05

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3462244

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:20:40

Generated On: 09 Jun 2021 17:44:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462244

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:17:51

Generated On: 09 Jun 2021 17:44:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462244

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:17:51

Generated On: 09 Jun 2021 17:44:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462244

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 19:13:50

Generated On: 09 Jun 2021 17:44:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462244

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:17:51

Generated On: 09 Jun 2021 17:44:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462244

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:20:40

Generated On: 09 Jun 2021 17:44:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462244

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:17:51

Generated On: 09 Jun 2021 17:44:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462244

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 19:13:50

Generated On: 09 Jun 2021 17:44:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 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

US3462244

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 30 Mar 2021 00:58:57

Generated On: 09 Jun 2021 17:44:05

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) _____

US3462244

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 19:13:50

Generated On: 09 Jun 2021 17:44:05

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.

US3462244

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Mar 2021 19:13:50

Generated On: 09 Jun 2021 17:44:05

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	17 MAR 2021
Collection time (00:00-23:59)	11:32 (24 HR)
Collection date and time (derived)	17 MAR 2021 11:32

US3462244

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 19:13:50

Generated On: 09 Jun 2021 17:44:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462244

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 22:56:19

Generated On: 09 Jun 2021 17:44:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462244

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 22:56:19

Generated On: 09 Jun 2021 17:44:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462244

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:05

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

US3462244

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:05

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

Date of Contact 01 NOV 2020

Time of Contact

Date and Time of Contact (derived)

Type of Contact

Clinic Visit - Scheduled ☐

Clinical Visit - Unscheduled ☐

Safety Call ☒

Convalescent Tele-visit ☐

Has the subject reported symptoms of SARS-COV-2?

Yes ☒

No ☐

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 30 Mar 2021 00:58:57

Generated On: 09 Jun 2021 17:44:05

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"/>

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 30 Mar 2021 00:58:57

Generated On: 09 Jun 2021 17:44:05

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	01 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

328 of 2707

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 30 Mar 2021 00:58:57

Generated On: 09 Jun 2021 17:44:05

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

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 30 Mar 2021 00:58:57

Generated On: 09 Jun 2021 17:44:05

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 type="radio"/>
	Mild	<input checked="" 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"/>

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 30 Mar 2021 00:58:57

Generated On: 09 Jun 2021 17:44:05

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"/>

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 30 Mar 2021 00:58:57

Generated On: 09 Jun 2021 17:44:05

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	02 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	36.8 C	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 30 Mar 2021 00:58:57

Generated On: 09 Jun 2021 17:44:05

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

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 30 Mar 2021 00:58:57

Generated On: 09 Jun 2021 17:44:05

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 type="radio"/>
	Mild	<input checked="" 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"/>

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Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 30 Mar 2021 00:58:57

Generated On: 09 Jun 2021 17:44:05

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 01 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 30 Mar 2021 00:58:57

Generated On: 09 Jun 2021 17:44:05

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	03 NOV 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Form: Symptom Log (3)

Data signed: (b) (4) 30 Mar 2021 00:58:57

Generated On: 09 Jun 2021 17:44:05

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 30 Mar 2021 00:58:57

Generated On: 09 Jun 2021 17:44:05

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 type="radio"/>
	Mild	<input checked="" 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 01 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 30 Mar 2021 00:58:57

Generated On: 09 Jun 2021 17:44:05

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 01 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 30 Mar 2021 00:58:57

Generated On: 09 Jun 2021 17:44:05

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	04 NOV 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
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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EAB) (1725)

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Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 30 Mar 2021 00:58:57

Generated On: 09 Jun 2021 17:44:05

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 30 Mar 2021 00:58:57

Generated On: 09 Jun 2021 17:44:05

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 type="radio"/>
	Mild	<input checked="" 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 01 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 30 Mar 2021 00:58:57

Generated On: 09 Jun 2021 17:44:05

Symptom Day

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

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Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 30 Mar 2021 00:58:57

Generated On: 09 Jun 2021 17:44:05

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	05 NOV 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 30 Mar 2021 00:58:57

Generated On: 09 Jun 2021 17:44:05

	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"/>

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 30 Mar 2021 00:58:57

Generated On: 09 Jun 2021 17:44:05

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 01 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 30 Mar 2021 00:58:57

Generated On: 09 Jun 2021 17:44:05

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"/>

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 30 Mar 2021 00:58:57

Generated On: 09 Jun 2021 17:44:05

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	06 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 30 Mar 2021 00:58:57

Generated On: 09 Jun 2021 17:44:05

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 30 Mar 2021 00:58:57

Generated On: 09 Jun 2021 17:44:05

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"/>

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

Date of Visit	02 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 type="radio"/> No <input checked="" type="radio"/>
Date of Test	02 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)	0

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Folder: Covid-19 Assessment 01 Nov 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

[Generate Next COVID-19 Assessment](#)

Yes ☒

No ☐

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

Date of Contact	04 DEC 2020
Time of Contact	14:00
Date and Time of Contact (derived)	04 DEC 2020 14:00
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

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Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

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"/>

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

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

Date	03 DEC 2020
------	-------------

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

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

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

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

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

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

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Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

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

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

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"/>

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	04 DEC 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

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

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Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

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

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Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

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"/>

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

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

Date	05 DEC 2020
------	-------------

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

O2 Saturation	
---------------	--

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

Temperature	
-------------	--

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

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

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

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 04 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	06 DEC 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (4)

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

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Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

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

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Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

Symptom Day

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

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Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	07 DEC 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.4 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Form: Symptom Log (5)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

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

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Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

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

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Form: Symptom Log (6)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

Symptom Day

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

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Form: Symptom Log (6)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	08 DEC 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	97.7 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Form: Symptom Log (6)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

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

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Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

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

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Form: Symptom Log (7)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

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) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	09 DEC 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.5 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (7)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

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

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Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

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

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Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

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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Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	10 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (8)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

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

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Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

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

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Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

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 04 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	11 DEC 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

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

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Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

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 04 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	12 DEC 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	98.8 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

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

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EAB) (1725)

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Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

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

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Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

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 04 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	13 DEC 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.0 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

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

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EAB) (1725)

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Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

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

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Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

Symptom Day

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

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Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

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

Date	14 DEC 2020
------	-------------

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

O2 Saturation	
---------------	--

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

Temperature	
-------------	--

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

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

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Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

Symptom Day

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

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Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	15 DEC 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	97.1 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
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EAB) (1725)		

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Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

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

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Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

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 04 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	16 DEC 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.7 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
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EAB) (1725)		

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Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

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

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EAB) (1725)

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Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

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

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Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

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 04 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

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

Date	17 DEC 2020
------	-------------

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

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

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

Temperature	97.5 F
-------------	--------

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

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

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

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

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Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

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

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EAB) (1725)

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Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

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

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Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

Symptom Day

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

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Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

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

Date	18 DEC 2020
------	-------------

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

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

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

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

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

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

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

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

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Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

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

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Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

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

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Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

Symptom Day

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

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Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

	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 DEC 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
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EAB) (1725)		

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Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

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

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Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

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

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 19 Feb 2021 20:17:50

Generated On: 09 Jun 2021 17:44:05

Date of Visit	07 DEC 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	07 DEC 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

US3462244

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 19 Feb 2021 20:17:51

Generated On: 09 Jun 2021 17:44:05

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	04 NOV 2020
Day 5	Yes	06 NOV 2020
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3462244

Folder: Illness Visit (2)

Form: Saliva Collection

Data signed: (b) (4) 19 Feb 2021 20:17:51

Generated On: 09 Jun 2021 17:44:05

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	09 DEC 2020
Day 5	Yes	11 DEC 2020
Day 7	Yes	13 DEC 2020
Day 9	Yes	15 DEC 2020
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3462244

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 20:17:51

Generated On: 09 Jun 2021 17:44:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 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

US3462244

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 20:17:51

Generated On: 09 Jun 2021 17:44:05

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	02 NOV 2020
Time of assessment (00:00-23:59)	13:05 (24 HR)
Vital Signs Date and Time (derived)	02 NOV 2020 13:05
Height (xxx.x)	158 cm
Weight (xxx.x)	45.5 kg
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3462244

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 20:17:51

Generated On: 09 Jun 2021 17:44:05

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.

US3462244

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 19 Feb 2021 20:17:51

Generated On: 09 Jun 2021 17:44:05

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

02 NOV 2020

US3462244

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 20:17:51

Generated On: 09 Jun 2021 17:44:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	07 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3462244

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 20:17:51

Generated On: 09 Jun 2021 17:44:05

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	07 DEC 2020
Time of assessment (<i>00:00-23:59</i>)	14:35 (24 HR)
Vital Signs Date and Time (derived)	07 DEC 2020 14:35
Height (<i>xxx.x</i>)	158 cm
Weight (<i>xxx.x</i>)	45 kg
Temperature (<i>xxx.x</i>)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	94 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	72 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3462244

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 20:17:51

Generated On: 09 Jun 2021 17:44:05

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

07 DEC 2020

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

US3462244

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 19 Feb 2021 20:17:51

Generated On: 09 Jun 2021 17:44:05

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

07 DEC 2020

US3462244

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

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 19:13:50

Generated On: 09 Jun 2021 17:44:05

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

Visit date (dd MMM yyyy)	22 JAN 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
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US3462244

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

Form: Unblinding

Data signed: (b) (4) 19 Mar 2021 19:13:50

Generated On: 09 Jun 2021 17:44:05

Date of updated informed consent (*dd MMM yyyy*) 22 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (*dd MMM yyyy*) 22 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3462244

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Mar 2021 19:13:49

Generated On: 09 Jun 2021 17:44:05

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 JAN 2021

Collection time (00:00-23:59)

11:48 (24 HR)

Collection date and time (derived)

22 JAN 2021 11:48

US3462244

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Mar 2021 19:13:49

Generated On: 09 Jun 2021 17:44:05

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 JAN 2021
Collection time (00:00 - 23:59)	11:34
Collection Date and Time (derived)	22 JAN 2021 11:34

US3462244

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 20:17:49

Generated On: 09 Jun 2021 17:44:05

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3462244

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Apr 2021 22:56:19

Generated On: 09 Jun 2021 17:44:05

AEID

Adverse event

UPPER RESPIRATORY TRACT
INFECTION

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

31 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

06 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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US3462244

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Apr 2021 22:56:19

Generated On: 09 Jun 2021 17:44:05

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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	PATIENT'S INITIAL SYMPTOMS WERE MILD COUGH, SORE THROAT, FATIGUE AND HEADACHE.
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 16 Apr 2021 22:56:19

Generated On: 09 Jun 2021 17:44:05

AEID

Adverse event

GASTROENTERITIS

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

03 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

19 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 16 Apr 2021 22:56:19

Generated On: 09 Jun 2021 17:44:05

Persistent or significant disability or incapacity False

Congenital anomaly or birth defect False

Other medically important event False

Relationship to investigational product Not Related ☒
Related ☐
Not Applicable ☐

Relationship to Study Procedure Not Related ☒
Related ☐
Not Applicable ☐

Action taken with investigational product None ☐
Dose Delayed ☐
Investigational Product ☐
Withdrawn ☐
Not Applicable ☒

Other action taken (check all that apply)

None False

Concomitant Medication True

Concomitant Procedure False

Outcome Fatal ☐
Not Recovered/Not Resolved ☐
Recovered/Resolved ☒
Recovered/Resolved with Sequelae ☐
Recovering/Resolving ☐
Unknown ☐

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Narrative

PATIENT REPORTED GI SYMPTOMS BEGINNING ON 03DEC2020 AND RESOLVED BY 10DEC2020. HOWEVER, DUE TO LABORATORY DELAYS WITH TESTING THE NASAL SWAB, NEGATIVE COVID-19 RESULT WAS NOT RETURNED UNTIL 19DEC2020.

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 16 Apr 2021 22:56:19

Generated On: 09 Jun 2021 17:44:05

Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 16 Apr 2021 22:56:19

Generated On: 09 Jun 2021 17:44:05

AEID	USA-US093-2021-MRNA-1273-P30 1000010
Adverse event	PREGNANCY ON STUDY
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)	12 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input 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	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 (3)

Data signed: (b) (4) 16 Apr 2021 22:56:19

Generated On: 09 Jun 2021 17:44:05

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

US3462244

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 16 Apr 2021 22:56:19

Generated On: 09 Jun 2021 17:44:05

PATIENT CONTACTED SITE TO
INFORM OF POSITIVE
PREGNANCY TEST DATED
12APR2021. PATIENT NOTICED
DELAYED MENSES, INCREASED
FREQUENCY OF URINATION,
AND ABDOMINAL SWELLING
LEADING TO HER VISITING HER
PCP. PATIENT HAD AN IUD
INSERTED IN 2018 AND
REMOVED IN DEC2020, BUT DID
NOT INFORM SITE OF IUD
REMOVAL. PATIENT REPORTED
WAITING 3 MONTHS AFTER
DAY 29 BEFORE REMOVING
IUD, WHICH CORRESPONDS TO
PROTOCOL INCLUSION
CRITERIA FOR FOCBP.

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)	

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Mar 2021 19:13:49

Generated On: 09 Jun 2021 17:44:05

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

Yes ☒

No ☐

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

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 30 Mar 2021 00:58:57

Generated On: 09 Jun 2021 17:44:05

Name of Medication PRESTIQUE

Prophylaxis Yes ☐
No ☒

Indication ANXIETY/DEPRESSION

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 30 Mar 2021 00:58:57

Generated On: 09 Jun 2021 17:44:05

	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 2018	
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"/>

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 30 Mar 2021 00:58:57

Generated On: 09 Jun 2021 17:44:05

Name of Medication WELLBUTRIN

Prophylaxis Yes ☐
No ☒

Indication ANXIETY/DEPRESSION

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 30 Mar 2021 00:58:57

Generated On: 09 Jun 2021 17:44:05

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN MAY 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	01 OCT 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 30 Mar 2021 00:58:57

Generated On: 09 Jun 2021 17:44:05

Name of Medication VALTREX

Prophylaxis Yes ☐
No ☒

Indication HSV-1

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 ☐
Intraocular ☐

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EAB) (1725)

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 30 Mar 2021 00:58:57

Generated On: 09 Jun 2021 17:44:05

	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 2018	
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"/>

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 30 Mar 2021 00:58:57

Generated On: 09 Jun 2021 17:44:05

Name of Medication WELLBUTRIN

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION/ANXIETY

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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EAB) (1725)

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 30 Mar 2021 00:58:57

Generated On: 09 Jun 2021 17:44:05

	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)		02 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		18 OCT 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"/>

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 30 Mar 2021 00:58:57

Generated On: 09 Jun 2021 17:44:05

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication INJECTION SITE PAIN/
HEADACHE

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 30 Mar 2021 00:58:57

Generated On: 09 Jun 2021 17:44:05

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		19 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 AUG 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 30 Mar 2021 00:58:57

Generated On: 09 Jun 2021 17:44:05

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication INJECTION SITE PAIN/
HEADACHE

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 30 Mar 2021 00:58:57

Generated On: 09 Jun 2021 17:44:05

	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)	16 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		17 SEP 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 30 Mar 2021 00:58:57

Generated On: 09 Jun 2021 17:44:05

Name of Medication IMMIDIUM

Prophylaxis Yes ☐
No ☒

Indication GASTROENTERITIS, DIARRHEA

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 30 Mar 2021 00:58:57

Generated On: 09 Jun 2021 17:44:05

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		03 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		03 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3462244

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:44:05

Were any concomitant procedures performed?

Yes ☐

No ☐

If yes, please complete Concomitant Procedures form.

US3462244

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:44:05

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

US3462244

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:44:05

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 ☐

US3462244

Folder: SAE USA-US093-2021-MRNA-1273-P301000010

Form: Safety Report Form

Data signed: (b) (4) 16 Apr 2021 22:56:19

Generated On: 09 Jun 2021 17:44:05

SAEID	USA-US093-2021-MRNA-1273-P301000010
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 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	GREGG
Investigator's Last Name	LUCKSINGER
Site Address: Street	1900 CYPRESS CREEK RD
Site Address: City	CEDAR PARK
Site Address: State	TX
Site Address: Postal Code	78613
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3462244

Folder: SAE USA-US093-2021-MRNA-1273-P301000010

Form: Safety Report Form (1)

Data signed: (b) (4) 16 Apr 2021 22:56:19

Generated On: 09 Jun 2021 17:44:05

SAEID	USA-US093-2021-MRNA-1273-P301000010
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 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	GREGG
Investigator's Last Name	LUCKSINGER
Site Address: Street	1900 CYPRESS CREEK RD
Site Address: City	CEDAR PARK
Site Address: State	TX
Site Address: Postal Code	78613
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	16/APR/2021 06:14
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

US3462244 (Prod: Crisor, LLC)

US3462244

Form: Participant Creation

Generated On: 09 Jun 2021 17:44:05

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'US3462244'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 17:39:24

US3462244

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:44:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	19 Aug 2020 18:39:05

US3462244

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '19 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 17:39:27

US3462244

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:44:05

[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 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'Clinic (Clinic)'	(b) (4) Danuel Hamlin (b) (4)	19 Aug 2020 18:39:05

US3462244

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:44:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User entered 'SCRN'	System	19 Aug 2020 18:39:05

US3462244

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:44:05

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered (b) (6) 1993'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 17:39:28

US3462244

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:44:05

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '27'	(b) (4) Danuel Hamlin (b) (4)	19 Aug 2020 18:39:35

US3462244

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:44:05

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User entered 'YEARS'	System	19 Aug 2020 18:39:35

US3462244

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:44:05

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User entered '27'	System	19 Aug 2020 18:40:08

US3462244

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:44:05

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'Female (F)'	(b) (4) Danuel Hamlin (b) (4)	19 Aug 2020 18:39:35

US3462244

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:44:05

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Danuel Hamlin (b) (4)	19 Aug 2020 18:39:35

US3462244

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:44:05

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'I'	(b) (4) Danuel Hamlin (b) (4)	19 Aug 2020 18:39:35

US3462244

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:44:05

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	19 Aug 2020 18:39:35

US3462244

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:44:05

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	19 Aug 2020 18:39:35

US3462244

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:44:05

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	19 Aug 2020 18:39:35

US3462244

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:44:05

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '0'	Danuel Hamlin (b) (4)	19 Aug 2020 18:39:35

US3462244

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:44:05

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	19 Aug 2020 18:39:35

US3462244

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:44:05

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	19 Aug 2020 18:39:35

US3462244

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:44:05

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	19 Aug 2020 18:39:35

US3462244

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:44:05

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	19 Aug 2020 18:39:35

US3462244

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:44:05

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '19 Aug 2020'	(b) (4) Danuel Hamlin (b) (4)	19 Aug 2020 18:40:08

US3462244

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User entered 'Aug 2020'	System	19 Aug 2020 18:40:08

US3462244

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User entered '2020'	System	19 Aug 2020 18:40:08

US3462244

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:44:05

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'Amendment 2 (2)'	Danuel Hamlin (b) (4)	19 Aug 2020 18:40:08

US3462244

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	19 Aug 2020 18:40:08

US3462244

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:44:05

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	19 Aug 2020 18:40:08

US3462244

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:44:05

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	19 Aug 2020 18:40:08

US3462244

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:44:05

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	19 Aug 2020 18:40:08

US3462244

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:44:05

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 17:39:27

US3462244

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:44:05

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User entered 'I'	System	19 Aug 2020 18:40:31

US3462244

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	19 Aug 2020 18:40:31

US3462244

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:44:05

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:10:44

US3462244

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:44:05

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergic rhinitis - version MedDRA\\23.0.	Coder Import (b) (4)	03 Nov 2020 23:59:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	03 Nov 2020 23:59:29
Data point term sent to Coder	System	03 Nov 2020 23:58:35
Coding entries removed.	Danuel Hamlin (b) (4)	03 Nov 2020 23:58:30
User entered 'Seasonal Allergic Rhinitis' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	03 Nov 2020 23:58:30
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergic rhinitis - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 09:11:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	(b) (4)	22 Aug 2020 09:11:16
Data point term sent to Coder	System	20 Aug 2020 20:11:38
User entered 'SAR'	(b) (4), (b) (6)	20 Aug 2020 20:11:36

US3462244

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'un UNK 2012'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:11:36

US3462244

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:44:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 20:11:36

US3462244

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:44:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:11:36

US3462244

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:11:36

US3462244

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:44:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:11:36

US3462244

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User entered 'Jan 2012'	System	20 Aug 2020 20:11:36

US3462244

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User entered '2012'	System	20 Aug 2020 20:11:36

US3462244

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User entered empty.	System	20 Aug 2020 20:11:36

US3462244

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User entered empty.	System	20 Aug 2020 20:11:36

US3462244

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:44:05

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User coded data point as SOC: Vascular disorders, HLGT: Arteriosclerosis, stenosis, vascular insufficiency and necrosis, HLT: Peripheral vasoconstriction, necrosis and vascular insufficiency, PT: Raynaud's phenomenon, LLT: Raynaud's syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 10:15:17
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 10:15:17
Data point term sent to Coder	System	20 Aug 2020 20:12:39
User entered 'Raynaud Syndrome'	(b) (4), (b) (6)	20 Aug 2020 20:11:59

US3462244

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'un UNK 2011'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:11:59

US3462244

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:44:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 20:11:59

US3462244

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:44:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:11:59

US3462244

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:11:59

US3462244

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:44:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:11:59

US3462244

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User entered 'Jan 2011'	System	20 Aug 2020 20:11:59

US3462244

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User entered '2011'	System	20 Aug 2020 20:11:59

US3462244

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User entered empty.	System	20 Aug 2020 20:11:59

US3462244

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User entered empty.	System	20 Aug 2020 20:11:59

US3462244

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:44:05

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 20:13:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 20:13:27
Data point term sent to Coder	System	20 Aug 2020 20:12:40
User entered 'Anxiety'	(b) (4), (b) (6)	20 Aug 2020 20:12:17

US3462244

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'un UNK 2008'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:12:17

US3462244

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:44:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:12:17

US3462244

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:44:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:12:17

US3462244

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:12:17

US3462244

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:44:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 20:12:17

US3462244

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User entered 'Jan 2008'	System	20 Aug 2020 20:12:17

US3462244

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User entered '2008'	System	20 Aug 2020 20:12:17

US3462244

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User entered empty.	System	20 Aug 2020 20:12:17

US3462244

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User entered empty.	System	20 Aug 2020 20:12:17

US3462244

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:44:05

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Sulfonamide allergy - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 23:19:20
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 23:19:20
Data point term sent to Coder	System	20 Aug 2020 20:12:40
User entered 'drug allergy to sulfa medications'	(b) (4), (b) (6)	20 Aug 2020 20:12:39

US3462244

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:12:39

US3462244

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:44:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:12:39

US3462244

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:44:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:12:39

US3462244

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:12:39

US3462244

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:44:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:12:39

US3462244

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User entered 'Jan 2018'	System	20 Aug 2020 20:12:39

US3462244

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User entered '2018'	System	20 Aug 2020 20:12:39

US3462244

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User entered empty.	System	20 Aug 2020 20:12:39

US3462244

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User entered empty.	System	20 Aug 2020 20:12:39

US3462244

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:44:05

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Herpes simplex, LLT: Herpes simplex type I - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 20:19:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 20:19:21
Data point term sent to Coder	System	20 Aug 2020 20:17:46
User entered 'HSV-1'	(b) (4), (b) (6)	20 Aug 2020 20:17:01

US3462244

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:17:01

US3462244

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:44:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 20:17:01

US3462244

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:44:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:17:01

US3462244

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:17:01

US3462244

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:44:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:17:01

US3462244

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User entered 'Jan 2018'	System	20 Aug 2020 20:17:01

US3462244

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User entered '2018'	System	20 Aug 2020 20:17:01

US3462244

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User entered empty.	System	20 Aug 2020 20:17:01

US3462244

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User entered empty.	System	20 Aug 2020 20:17:01

US3462244

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:44:05

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User coded data point as SOC: Psychiatric disorders, HLG: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 00:00:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 00:00:28
Data point term sent to Coder	System	03 Nov 2020 23:59:35
User entered 'Depression'	Daniel Hamlin (b) (4)	03 Nov 2020 23:59:08

US3462244

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'un UNK 2008'	(b) (4) Danuel Hamlin (b) (4)	03 Nov 2020 23:59:08

US3462244

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:44:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	03 Nov 2020 23:59:08

US3462244

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:44:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	03 Nov 2020 23:59:08

US3462244

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:44:05

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	03 Nov 2020 23:59:08

US3462244

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:44:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	03 Nov 2020 23:59:08

US3462244

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User entered 'Jan 2008'	System	03 Nov 2020 23:59:08

US3462244

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User entered '2008'	System	03 Nov 2020 23:59:08

US3462244

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User entered empty.	System	03 Nov 2020 23:59:08

US3462244

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User entered empty.	System	03 Nov 2020 23:59:08

US3462244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:22:47

US3462244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '19 Aug 2020'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:22:47

US3462244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '10:44'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:22:47

US3462244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User entered '19 Aug 2020 10:44'	System	20 Aug 2020 21:22:47

US3462244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '158' cm	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:22:47
DataPoint set to visible.	System	19 Aug 2020 18:40:31

US3462244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '45' kg	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:22:47
DataPoint set to visible.	System	19 Aug 2020 18:40:31

US3462244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
Amendment Manager: User entered '18.02596'	System	17 Sep 2020 00:14:26
User entered '18.0'	System	20 Aug 2020 21:22:47
DataPoint set to visible.	System	19 Aug 2020 18:40:31

US3462244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User entered 'kg/m2'	System	20 Aug 2020 21:22:47
DataPoint set to visible.	System	19 Aug 2020 18:40:31

US3462244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:00:44
User entered '98.1' F		20 Aug 2020 21:22:47

US3462244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:00:44
User entered 'Other (Other)'		20 Aug 2020 21:22:47

US3462244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:00:44
User entered 'tympanic'		20 Aug 2020 21:22:47

US3462244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:00:44
User entered '88'		20 Aug 2020 21:22:47

US3462244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User entered 'bpm'	System	20 Aug 2020 21:22:47

US3462244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:00:44
User entered '16'		20 Aug 2020 21:22:47

US3462244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User entered 'breaths/min'	System	20 Aug 2020 21:22:47

US3462244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:00:44
User entered '94'		20 Aug 2020 21:22:47

US3462244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User entered 'mmHg'	System	20 Aug 2020 21:22:47

US3462244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:00:44
User entered '62'		20 Aug 2020 21:22:47

US3462244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User entered 'mmHg'	System	20 Aug 2020 21:22:47

US3462244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32

US3462244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32

US3462244

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:44:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:22:56

US3462244

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:44:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	24 Sep 2020 11:24:03
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	16 Sep 2020 19:18:34
User entered '19 Aug 2020'	(b) (4), (b) (6)	20 Aug 2020 21:22:56

US3462244

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:44:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '19 Aug 2020'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:23:12

US3462244

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:44:05

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:23:12

US3462244

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:44:05

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 21:23:12

US3462244

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:44:05

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:23:12

US3462244

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:23:12

US3462244

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:44:05

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:23:12

US3462244

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:23:12

US3462244

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:44:05

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:23:12

US3462244

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:44:05

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:23:31

US3462244

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:44:05

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '19 Aug 2020'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:23:31

US3462244

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:44:05

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:23:31

US3462244

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:44:05

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:23:31

US3462244

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:44:05

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:23:31

US3462244

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:44:05

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 21:23:31

US3462244

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:44:05

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 21:23:31

US3462244

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:44:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User entered empty.	System	20 Aug 2020 21:23:31

US3462244

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:44:05

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 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:24:40

US3462244

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:44:05

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 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:24:40

US3462244

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:44:05

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 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:24:40

US3462244

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:44:05

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 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:24:40

US3462244

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:44:05

[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 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:24:40

US3462244

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:44:05

[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 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:24:40

US3462244

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:44:05

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 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:24:40

US3462244

Folder: Screening

Form: Risk of Exposure

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Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:24:40

US3462244

Folder: Screening

Form: Risk of Exposure

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[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 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:24:40

US3462244

Folder: Screening

Form: Risk of Exposure

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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 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:24:40

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Folder: Screening

Form: Risk of Exposure

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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 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:24:40

US3462244

Folder: Screening

Form: Risk of Exposure

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:24:40

US3462244

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:44:05

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 21:24:40

US3462244

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:44:05

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:24:40

US3462244

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:44:05

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:24:40

US3462244

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:44:05

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 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:24:40

US3462244

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:44:05

[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 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:24:40

US3462244

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:44:05

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 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 21:24:40

US3462244

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:44:05

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'I'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:24:40

US3462244

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:44:05

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'I'	(b) (4), (b) (6)	20 Aug 2020 21:24:40

US3462244

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:44:05

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'frequent trips to grocery store'	(b) (4), (b) (6)	20 Aug 2020 21:24:40

US3462244

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:44:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	19 Aug 2020 18:41:02

US3462244

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:44:05

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '19 Aug 2020'	(b) (4) Danuel Hamlin (b) (4)	19 Aug 2020 18:41:02

US3462244

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'Clinic (Clinic)'	(b) (4) Danuel Hamlin (b) (4)	19 Aug 2020 18:41:02

US3462244

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:44:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User entered 'VISIT1'	System	19 Aug 2020 18:41:02

US3462244

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '19 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 17:54:25

US3462244

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:44:05

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 05:38:00
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:38:00
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Aug 2020 17:54:25
User entered '105915' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 17:54:25

US3462244

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:44:05

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 17:54:25

US3462244

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:44:05

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)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User closed query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:22:45
Query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' answered with 'Added' (Site from DM).	Danuel Hamlin (b) (4)	04 Nov 2020 00:45:58
User entered 'No (N)'	Danuel Hamlin (b) (4)	03 Nov 2020 23:40:17
User opened query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 14:24:55

US3462244

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:44:05

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)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'No (N)'	Danuel Hamlin (b) (4)	03 Nov 2020 23:40:17

US3462244

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:44:05

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	03 Nov 2020 23:40:17

US3462244

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:44:05

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	03 Nov 2020 23:40:17

US3462244

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:44:05

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	03 Nov 2020 23:40:17

US3462244

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:44:05

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	03 Nov 2020 23:40:17
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:36:01
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:34:07

US3462244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:44:05

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User closed query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:28:35
User entered missing code ND - Not Done; reason for change Data Entry Error		04 Nov 2020 20:01:01
Query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' answered with 'Removed' (Site from DM).	Danuel Hamlin (b) (4)	04 Nov 2020 00:51:36
User entered empty; reason for change Data Entry Error	Danuel Hamlin (b) (4)	04 Nov 2020 00:51:26
User opened query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 10:47:11
User entered '158' cm		20 Aug 2020 21:26:24

US3462244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:44:05

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	04 Nov 2020 20:01:01
User entered empty; reason for change Data Entry Error	Danuel Hamlin (b) (4)	04 Nov 2020 00:51:26
User entered '45' kg	(b) (4), (b) (6)	20 Aug 2020 21:26:24

US3462244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:44:05

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User closed query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:28:35
User entered missing code ND - Not Done; reason for change Data Entry Error		04 Nov 2020 20:01:01
Query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' answered with 'Removed' (Site from DM).	Danuel Hamlin (b) (4)	04 Nov 2020 00:51:36
User entered empty; reason for change Data Entry Error	Danuel Hamlin (b) (4)	04 Nov 2020 00:51:26
User opened query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 10:47:11
User entered '158' cm		20 Aug 2020 21:26:24

US3462244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:44:05

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	04 Nov 2020 20:01:01
User entered empty; reason for change Data Entry Error	Danuel Hamlin (b) (4)	04 Nov 2020 00:51:26
User entered '45' kg	(b) (4), (b) (6)	20 Aug 2020 21:26:24

US3462244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User accepted default value 'Pre-Dose (PREDOSE)'		20 Aug 2020 21:26:24

US3462244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:26:24

US3462244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '19 Aug 2020'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:26:24

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '10:44'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:26:24

US3462244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User entered '19 Aug 2020 10:44'	System	20 Aug 2020 21:26:24

US3462244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '98.1' F	(b) (4), (b) (6)	20 Aug 2020 21:26:24

US3462244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:26:24

US3462244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'tympanic'	(b) (4), (b) (6)	20 Aug 2020 21:26:24

US3462244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '88'	(b) (4), (b) (6)	20 Aug 2020 21:26:24

US3462244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User entered 'bpm'	System	20 Aug 2020 21:26:24

US3462244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '16'	(b) (4), (b) (6)	20 Aug 2020 21:26:24

US3462244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User entered 'breaths/min'	System	20 Aug 2020 21:26:24

US3462244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '94'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:26:24

US3462244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User entered 'mmHg'	System	20 Aug 2020 21:26:24

US3462244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '62'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:26:24

US3462244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:05

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User entered 'mmHg'	System	20 Aug 2020 21:26:24

US3462244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:44:05

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User closed query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:28:35
User entered missing code ND - Not Done; reason for change Data Entry Error		04 Nov 2020 20:01:01
Query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' answered with 'Removed' (Site from DM).	Danuel Hamlin (b) (4)	04 Nov 2020 00:51:36
User entered empty; reason for change Data Entry Error	Danuel Hamlin (b) (4)	04 Nov 2020 00:51:26
User opened query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 10:47:11
User entered '158' cm		20 Aug 2020 21:26:24

US3462244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:44:05

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	04 Nov 2020 20:01:01
User entered empty; reason for change Data Entry Error	Danuel Hamlin (b) (4)	04 Nov 2020 00:51:26
User entered '45' kg	(b) (4), (b) (6)	20 Aug 2020 21:26:24

US3462244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User accepted default value 'Post-Dose (POSTDOSE)'		20 Aug 2020 21:27:37

US3462244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:27:37

US3462244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '19 Aug 2020'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:27:37

US3462244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 05:37:56
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'time confirmed' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 21:27:45
User opened 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).	System	20 Aug 2020 21:27:37
User entered '11:52'	(b) (4), (b) (6)	20 Aug 2020 21:27:37

US3462244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User entered '19 Aug 2020 11:52'	System	20 Aug 2020 21:27:37

US3462244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '98.4' F	(b) (4), (b) (6)	20 Aug 2020 21:27:37

US3462244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:27:37

US3462244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'tympanic'	(b) (4), (b) (6)	20 Aug 2020 21:27:37

US3462244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '82'	(b) (4), (b) (6)	20 Aug 2020 21:27:37

US3462244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User entered 'bpm'	System	20 Aug 2020 21:27:37

US3462244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '14'	(b) (4), (b) (6)	20 Aug 2020 21:27:37

US3462244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User entered 'breaths/min'	System	20 Aug 2020 21:27:37

US3462244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '102'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:27:37

US3462244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User entered 'mmHg'	System	20 Aug 2020 21:27:37

US3462244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '64'	(b) (4), (b) (6)	20 Aug 2020 21:27:37

US3462244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:05

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User entered 'mmHg'	System	20 Aug 2020 21:27:37

US3462244

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:44:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:28:32

US3462244

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:44:05

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '19 Aug 2020'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:28:32

US3462244

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:44:05

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User closed query 'Per CDM: per CCGs pages 15-16, please record this as NO and remove date as this pregnancy test is already recorded at Screening visit.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:20:32
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Nov 2020 00:25:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Nov 2020 00:25:43
User entered 'No (N)' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	04 Nov 2020 00:25:43
Query 'Per CDM: per CCGs pages 15-16, please record this as NO and remove date as this pregnancy test is already recorded at Screening visit.' answered with 'Removed' (Site from DM).	Danuel Hamlin (b) (4)	04 Nov 2020 00:25:31
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Nov 2020 00:24:32
User entered empty; reason for change Data Entry Error	Danuel Hamlin (b) (4)	04 Nov 2020 00:24:32
User entered 'No (N)' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	04 Nov 2020 00:24:05
User opened query 'Per CDM: per CCGs pages 15-16, please record this as NO and remove date as this pregnancy test is already recorded at Screening visit.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 07:27:58
User entered 'Yes (Y)'		20 Aug 2020 21:28:45

US3462244

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:44:05

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered empty; reason for change Data Entry Error	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 00:24:05
User entered '19 Aug 2020'	(b) (4), (b) (6)	20 Aug 2020 21:28:45

US3462244

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:44:05

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered empty; reason for change Data Entry Error	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 00:24:05
User entered 'Urine (URINE)'	(b) (4), (b) (6)	20 Aug 2020 21:28:45

US3462244

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:44:05

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered empty; reason for change Data Entry Error	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 00:24:05
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	20 Aug 2020 21:28:45

US3462244

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:44:05

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User closed query 'Per CDM: Response is required, kindly update as Yes/No' (Site from DM).	(b) (4)	
Query 'Per CDM: Response is required, kindly update as Yes/No' answered with 'Corrected' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 07:30:37
		18 Nov 2020 21:47:06
User entered 'No (N)' reason for change: Data Entry Error		18 Nov 2020 21:46:56
User opened query 'Per CDM: Response is required, kindly update as Yes/No' (Site from DM).		11 Nov 2020 15:30:22
User entered empty; reason for change Data Entry Error	Danuel Hamlin (b) (4)	04 Nov 2020 00:24:05
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 21:28:45

US3462244

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:44:05

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:28:45

US3462244

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:44:05

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 21:28:45

US3462244

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:44:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User entered empty.	System	20 Aug 2020 21:28:45

US3462244

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:44:05

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	19 Aug 2020 18:42:58

US3462244

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:44:05

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	19 Aug 2020 18:42:58

US3462244

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:44:05

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 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered empty.	Danuel Hamlin (b) (4)	19 Aug 2020 18:42:58

US3462244

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:44:05

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User entered 'MRNA-1273 OR PLACEBO'	System	19 Aug 2020 18:42:58

US3462244

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:44:05

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '19 Aug 2020'	(b) (4) Danuel Hamlin (b) (4)	19 Aug 2020 18:42:58

US3462244

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:44:05

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '11:21'	(b) (4) Danuel Hamlin (b) (4)	19 Aug 2020 18:42:58

US3462244

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:44:05

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User entered '19 Aug 2020 11:21'	System	19 Aug 2020 18:42:58

US3462244

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:44:05

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'Left Arm (LEFT ARM)'	(b) (4) Danuel Hamlin (b) (4)	19 Aug 2020 18:42:58

US3462244

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:44:05

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User entered 'ONCE'	System	19 Aug 2020 18:42:58

US3462244

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:44:05

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User entered 'INTRAMUSCULAR'	System	19 Aug 2020 18:42:58

US3462244

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:44:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:29:04

US3462244

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:44:05

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '19 Aug 2020'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:29:04

US3462244

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:44:05

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '11:14'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:29:04

US3462244

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:44:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User entered '19 Aug 2020 11:14'	System	20 Aug 2020 21:29:04

US3462244

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:44:05

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:37
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '19 Aug 2020'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:29:22

US3462244

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:44:05

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:37
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		20 Aug 2020 21:29:22

US3462244

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:44:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:37
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:29:22

US3462244

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:44:05

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:37
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '11:17'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:29:22

US3462244

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:44:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:37
User entered '19 Aug 2020 11:17'	System	20 Aug 2020 21:29:22

US3462244

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:44:05

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:37
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		20 Aug 2020 21:29:22

US3462244

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:44:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:37
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:29:22

US3462244

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:44:05

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:37
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:29:22

US3462244

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:44:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:37
User entered empty.	System	20 Aug 2020 21:29:22

US3462244

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:44:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:37
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:10:23

US3462244

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:44:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:37
User entered 'I'	System	20 Aug 2020 20:10:23

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
Data entry locked.	System	19 Aug 2020 18:42:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:44:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-19T11:53:39', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'c985d462-768e-4f42-bfd0-39dc59c64540'	System	19 Aug 2020 18:54:10
User entered 'Yes (Y)'	System	19 Aug 2020 18:54:10

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:44:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-19T11:53:46', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'c985d462-768e-4f42-bfd0-39dc59c64540'	System	19 Aug 2020 18:54:10
User entered '98.4'	System	19 Aug 2020 18:54:10

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-19T11:54:03', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'c985d462-768e-4f42-bfd0-39dc59c64540'	System	19 Aug 2020 18:54:10
User entered 'No (N)'	System	19 Aug 2020 18:54:10

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:44:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-19T11:54:08', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'c985d462-768e-4f42-bfd0-39dc59c64540'	System	19 Aug 2020 18:54:10
User entered '19 Aug 2020 11:54'	System	19 Aug 2020 18:54:10

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:44:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '19 Aug 2020 11:41'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:44:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '19 Aug 2020 14:11'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
Data entry locked.	System	19 Aug 2020 18:42:58
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-19T22:06:02', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '4a7b90f1-a517-4552-98a5-c361817dedf1'	System	20 Aug 2020 05:06:54
User entered 'Yes (Y)'	System	20 Aug 2020 05:06:54

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-19T22:06:06', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '4a7b90f1-a517-4552-98a5-c361817dedf1'	System	20 Aug 2020 05:06:54
User entered '98.8'	System	20 Aug 2020 05:06:54

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-19T22:06:13', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '4a7b90f1-a517-4552-98a5-c361817dedf1'	System	20 Aug 2020 05:06:54
User entered 'Yes (Y)'	System	20 Aug 2020 05:06:54

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Added' (Site from System).		12 Nov 2020 20:23:07
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Danuel Hamlin (b) (4)	04 Nov 2020 00:03:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-19T22:06:21', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '4a7b90f1-a517-4552-98a5-c361817dedf1'		
User entered '1'	System	20 Aug 2020 05:06:54

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-19T22:06:21', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '4a7b90f1-a517-4552-98a5-c361817dedf1'	System	20 Aug 2020 05:06:54
User entered '0'	System	20 Aug 2020 05:06:54

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-19T22:06:52', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '4a7b90f1-a517-4552-98a5-c361817dedf1'	System	20 Aug 2020 05:06:54
User entered '19 Aug 2020 22:06'	System	20 Aug 2020 05:06:54

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '19 Aug 2020 15:06'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
Data entry locked.	System	19 Aug 2020 18:42:58
User entered 'Day 2'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:44:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-20T22:28:53', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '6f73979f-7329-48a9-98f8-86aa85f6cd50'	System	21 Aug 2020 05:29:26
User entered 'Yes (Y)'	System	21 Aug 2020 05:29:26

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:44:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-20T22:29:05', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '6f73979f-7329-48a9-98f8-86aa85f6cd50'	System	21 Aug 2020 05:29:26
User entered '99.1'	System	21 Aug 2020 05:29:26

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-20T22:29:09', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '6f73979f-7329-48a9-98f8-86aa85f6cd50'	System	21 Aug 2020 05:29:26
User entered 'Yes (Y)'	System	21 Aug 2020 05:29:26

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Added' (Site from System).		12 Nov 2020 20:23:13
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Danuel Hamlin (b) (4)	04 Nov 2020 00:11:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-20T22:29:20', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '6f73979f-7329-48a9-98f8-86aa85f6cd50'		
User entered '1'	System	21 Aug 2020 05:29:26
	System	21 Aug 2020 05:29:26
	System	21 Aug 2020 05:29:26

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:44:05

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-20T22:29:20', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '6f73979f-7329-48a9-98f8-86aa85f6cd50'	System	21 Aug 2020 05:29:26
User entered '0'	System	21 Aug 2020 05:29:26

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:44:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-20T22:29:24', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '6f73979f-7329-48a9-98f8-86aa85f6cd50'	System	21 Aug 2020 05:29:26
User entered '20 Aug 2020 22:29'	System	21 Aug 2020 05:29:26

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:44:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:44:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
Data entry locked.	System	19 Aug 2020 18:42:58
User entered 'Day 3'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:44:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-21T23:59:33', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'e8432663-b90b-4a11-9713-cde822452b13'	System	22 Aug 2020 06:59:50
User entered 'Yes (Y)'	System	22 Aug 2020 06:59:50

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:44:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-21T23:59:40', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'e8432663-b90b-4a11-9713-cde822452b13'	System	22 Aug 2020 06:59:50
User entered '99.2'	System	22 Aug 2020 06:59:50

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-21T23:59:43', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'e8432663-b90b-4a11-9713-cde822452b13'	System	22 Aug 2020 06:59:50
User entered 'No (N)'	System	22 Aug 2020 06:59:50

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:44:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-21T23:59:47', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'e8432663-b90b-4a11-9713-cde822452b13'	System	22 Aug 2020 06:59:50
User entered '21 Aug 2020 23:59'	System	22 Aug 2020 06:59:50

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:44:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:44:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
Data entry locked.	System	19 Aug 2020 18:42:58
User entered 'Day 4'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:44:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-22T22:41:31', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '6962c677-908f-4cb6-adc1-38f1fca80ea5'	System	23 Aug 2020 05:41:50
User entered 'Yes (Y)'	System	23 Aug 2020 05:41:50

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:44:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-22T22:41:37', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '6962c677-908f-4cb6-adc1-38f1fca80ea5'	System	23 Aug 2020 05:41:50
User entered '98.7'	System	23 Aug 2020 05:41:50

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-22T22:41:42', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '6962c677-908f-4cb6-adc1-38f1fca80ea5'	System	23 Aug 2020 05:41:50
User entered 'No (N)'	System	23 Aug 2020 05:41:50

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:44:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-22T22:41:48', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '6962c677-908f-4cb6-adc1-38f1fca80ea5'	System	23 Aug 2020 05:41:50
User entered '22 Aug 2020 22:41'	System	23 Aug 2020 05:41:50

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:44:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:44:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
Data entry locked.	System	19 Aug 2020 18:42:58
User entered 'Day 5'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:44:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-24T00:00:01', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '22ecaa9e-e269-4169-b60f-a969aad361bb'	System	24 Aug 2020 07:00:20
User entered 'Yes (Y)'	System	24 Aug 2020 07:00:20

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:44:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-24T00:00:11', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '22ecaa9e-e269-4169-b60f-a969aad361bb'	System	24 Aug 2020 07:00:20
User entered '98.7'	System	24 Aug 2020 07:00:20

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-24T00:00:14', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '22ecaa9e-e269-4169-b60f-a969aad361bb'	System	24 Aug 2020 07:00:20
User entered 'No (N)'	System	24 Aug 2020 07:00:20

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:44:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-24T00:00:18', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '22ecaa9e-e269-4169-b60f-a969aad361bb'	System	24 Aug 2020 07:00:20
User entered '24 Aug 2020 00:00'	System	24 Aug 2020 07:00:20

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:44:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:44:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
Data entry locked.	System	19 Aug 2020 18:42:58
User entered 'Day 6'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:44:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-25T00:00:15', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'd9e70899-104c-4fad-b259-96e313ba0c75'	System	25 Aug 2020 07:00:57
User entered 'Yes (Y)'	System	25 Aug 2020 07:00:57

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:44:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-25T00:00:24', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'd9e70899-104c-4fad-b259-96e313ba0c75'	System	25 Aug 2020 07:00:57
User entered '98.9'	System	25 Aug 2020 07:00:57

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-25T00:00:52', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'd9e70899-104c-4fad-b259-96e313ba0c75'	System	25 Aug 2020 07:00:57
User entered 'No (N)'	System	25 Aug 2020 07:00:57

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:44:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-25T00:00:55', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'd9e70899-104c-4fad-b259-96e313ba0c75'	System	25 Aug 2020 07:00:57
User entered '25 Aug 2020 00:00'	System	25 Aug 2020 07:00:57

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:44:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:44:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
Data entry locked.	System	19 Aug 2020 18:42:58
User entered 'Day 7'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:44:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-25T21:47:34', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '16f5e796-d195-4591-bee5-f87cb8638e32'	System	26 Aug 2020 04:47:51
User entered 'Yes (Y)'	System	26 Aug 2020 04:47:51

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:44:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-25T21:47:41', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '16f5e796-d195-4591-bee5-f87cb8638e32'	System	26 Aug 2020 04:47:51
User entered '99.4'	System	26 Aug 2020 04:47:51

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-25T21:47:44', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '16f5e796-d195-4591-bee5-f87cb8638e32'	System	26 Aug 2020 04:47:51
User entered 'No (N)'	System	26 Aug 2020 04:47:51

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:44:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-25T21:47:48', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '16f5e796-d195-4591-bee5-f87cb8638e32'	System	26 Aug 2020 04:47:51
User entered '25 Aug 2020 21:47'	System	26 Aug 2020 04:47:51

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:44:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:44:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
Data entry locked.	System	19 Aug 2020 18:42:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:44:05

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 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-19T11:52:00', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'e3efd3e5-a8a9-4cfc-8f59-f5393b1f0ca0'	System	19 Aug 2020 18:53:29
User entered 'Does not interfere with activity (2)'	System	19 Aug 2020 18:53:29

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-19T11:52:39', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'e3efd3e5-a8a9-4cfc-8f59-f5393b1f0ca0'	System	19 Aug 2020 18:53:29
User entered 'No (N)'	System	19 Aug 2020 18:53:29

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-19T11:52:48', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'e3efd3e5-a8a9-4cfc-8f59-f5393b1f0ca0'	System	19 Aug 2020 18:53:29
User entered 'No (N)'	System	19 Aug 2020 18:53:29

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:44:05

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 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-19T11:53:06', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'e3efd3e5-a8a9-4cfc-8f59-f5393b1f0ca0'	System	19 Aug 2020 18:53:29
User entered 'None (1)'	System	19 Aug 2020 18:53:29

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:44:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-19T11:53:25', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'e3efd3e5-a8a9-4cfc-8f59-f5393b1f0ca0'	System	19 Aug 2020 18:53:29
User entered '19 Aug 2020 11:53'	System	19 Aug 2020 18:53:29

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:44:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '19 Aug 2020 11:41'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:44:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '19 Aug 2020 14:11'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
Data entry locked.	System	19 Aug 2020 18:42:58
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

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 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-19T22:07:16', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '55fed057-23ef-42f5-9acb-020de46d0ad6'	System	20 Aug 2020 05:07:40
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	20 Aug 2020 05:07:40

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-19T22:07:19', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '55fed057-23ef-42f5-9acb-020de46d0ad6'	System	20 Aug 2020 05:07:40
User entered 'No (N)'	System	20 Aug 2020 05:07:40

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-19T22:07:26', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '55fed057-23ef-42f5-9acb-020de46d0ad6'	System	20 Aug 2020 05:07:40
User entered 'No (N)'	System	20 Aug 2020 05:07:40

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

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 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-19T22:07:34', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '55fed057-23ef-42f5-9acb-020de46d0ad6'	System	20 Aug 2020 05:07:40
User entered 'None (1)'	System	20 Aug 2020 05:07:40

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-19T22:07:38', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '55fed057-23ef-42f5-9acb-020de46d0ad6'	System	20 Aug 2020 05:07:40
User entered '19 Aug 2020 22:07'	System	20 Aug 2020 05:07:40

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '19 Aug 2020 15:06'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
Data entry locked.	System	19 Aug 2020 18:42:58
User entered 'Day 2'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:44:05

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 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-20T22:29:57', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'd0d6ca93-985d-4ae7-914d-0d29d540f567'	System	21 Aug 2020 05:30:43
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	21 Aug 2020 05:30:43

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-20T22:30:00', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'd0d6ca93-985d-4ae7-914d-0d29d540f567'	System	21 Aug 2020 05:30:43
User entered 'No (N)'	System	21 Aug 2020 05:30:43

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-20T22:30:11', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'd0d6ca93-985d-4ae7-914d-0d29d540f567'	System	21 Aug 2020 05:30:43
User entered 'No (N)'	System	21 Aug 2020 05:30:43

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:44:05

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 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-20T22:30:28', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'd0d6ca93-985d-4ae7-914d-0d29d540f567'	System	21 Aug 2020 05:30:43
User entered 'None (1)'	System	21 Aug 2020 05:30:43

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:44:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-20T22:30:39', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'd0d6ca93-985d-4ae7-914d-0d29d540f567'	System	21 Aug 2020 05:30:43
User entered '20 Aug 2020 22:30'	System	21 Aug 2020 05:30:43

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:44:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:44:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
Data entry locked.	System	19 Aug 2020 18:42:58
User entered 'Day 3'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:44:05

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 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-21T23:58:50', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '09f1aaf2-b23c-486e-9c6c-99ede02dad47'	System	22 Aug 2020 06:59:03
User entered 'Does not interfere with activity (2)'	System	22 Aug 2020 06:59:03

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-21T23:58:53', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '09f1aaf2-b23c-486e-9c6c-99ede02dad47'	System	22 Aug 2020 06:59:03
User entered 'No (N)'	System	22 Aug 2020 06:59:03

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-21T23:58:55', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '09f1aaf2-b23c-486e-9c6c-99ede02dad47'	System	22 Aug 2020 06:59:03
User entered 'No (N)'	System	22 Aug 2020 06:59:03

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:44:05

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 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-21T23:58:58', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '09f1aaf2-b23c-486e-9c6c-99ede02dad47'	System	22 Aug 2020 06:59:03
User entered 'None (1)'	System	22 Aug 2020 06:59:03

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:44:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-21T23:59:02', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '09f1aaf2-b23c-486e-9c6c-99ede02dad47'	System	22 Aug 2020 06:59:03
User entered '21 Aug 2020 23:59'	System	22 Aug 2020 06:59:03

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:44:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:44:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
Data entry locked.	System	19 Aug 2020 18:42:58
User entered 'Day 4'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:44:05

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 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-22T22:41:59', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '87caf877-5132-4bf1-a838-64c886fc410d'	System	23 Aug 2020 05:42:31
User entered 'None (1)'	System	23 Aug 2020 05:42:31

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-22T22:42:03', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '87caf877-5132-4bf1-a838-64c886fc410d'	System	23 Aug 2020 05:42:31
User entered 'No (N)'	System	23 Aug 2020 05:42:31

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-22T22:42:06', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '87caf877-5132-4bf1-a838-64c886fc410d'	System	23 Aug 2020 05:42:31
User entered 'No (N)'	System	23 Aug 2020 05:42:31

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:44:05

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 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-22T22:42:16', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '87caf877-5132-4bf1-a838-64c886fc410d'	System	23 Aug 2020 05:42:31
User entered 'None (1)'	System	23 Aug 2020 05:42:31

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:44:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-22T22:42:26', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '87caf877-5132-4bf1-a838-64c886fc410d'	System	23 Aug 2020 05:42:31
User entered '22 Aug 2020 22:42'	System	23 Aug 2020 05:42:31

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:44:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:44:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
Data entry locked.	System	19 Aug 2020 18:42:58
User entered 'Day 5'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:44:05

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 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-24T00:00:26', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '1b3bc96f-ef60-4cda-a026-2c221e3b18a7'	System	24 Aug 2020 07:00:41
User entered 'None (1)'	System	24 Aug 2020 07:00:41

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-24T00:00:28', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '1b3bc96f-ef60-4cda-a026-2c221e3b18a7'	System	24 Aug 2020 07:00:41
User entered 'No (N)'	System	24 Aug 2020 07:00:41

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-24T00:00:31', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '1b3bc96f-ef60-4cda-a026-2c221e3b18a7'	System	24 Aug 2020 07:00:41
User entered 'No (N)'	System	24 Aug 2020 07:00:41

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:44:05

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 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-24T00:00:36', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '1b3bc96f-ef60-4cda-a026-2c221e3b18a7'	System	24 Aug 2020 07:00:41
User entered 'None (1)'	System	24 Aug 2020 07:00:41

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:44:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-24T00:00:39', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '1b3bc96f-ef60-4cda-a026-2c221e3b18a7'	System	24 Aug 2020 07:00:41
User entered '24 Aug 2020 00:00'	System	24 Aug 2020 07:00:41

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:44:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:44:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
Data entry locked.	System	19 Aug 2020 18:42:58
User entered 'Day 6'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:44:05

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 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-25T00:01:00', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '9947b9ac-35c8-4717-af4f-939f5ff1036b'	System	25 Aug 2020 07:01:11
User entered 'None (1)'	System	25 Aug 2020 07:01:11

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:44:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-25T00:01:02', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '9947b9ac-35c8-4717-af4f-939f5ff1036b'	System	25 Aug 2020 07:01:11
User entered 'No (N)'	System	25 Aug 2020 07:01:11

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-25T00:01:04', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '9947b9ac-35c8-4717-af4f-939f5ff1036b'	System	25 Aug 2020 07:01:11
User entered 'No (N)'	System	25 Aug 2020 07:01:11

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:44:05

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 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-25T00:01:06', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '9947b9ac-35c8-4717-af4f-939f5ff1036b'	System	25 Aug 2020 07:01:11
User entered 'None (1)'	System	25 Aug 2020 07:01:11

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:44:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-25T00:01:09', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '9947b9ac-35c8-4717-af4f-939f5ff1036b'	System	25 Aug 2020 07:01:11
User entered '25 Aug 2020 00:01'	System	25 Aug 2020 07:01:11

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:44:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:44:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
Data entry locked.	System	19 Aug 2020 18:42:58
User entered 'Day 7'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:44:05

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 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-25T21:46:39', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'ec02de19-eba3-4412-9d56-483b934ccaf7'	System	26 Aug 2020 04:46:53
User entered 'None (1)'	System	26 Aug 2020 04:46:53

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-25T21:46:42', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'ec02de19-eba3-4412-9d56-483b934ccaf7'	System	26 Aug 2020 04:46:53
User entered 'No (N)'	System	26 Aug 2020 04:46:53

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-25T21:46:45', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'ec02de19-eba3-4412-9d56-483b934ccaf7'	System	26 Aug 2020 04:46:53
User entered 'No (N)'	System	26 Aug 2020 04:46:53

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:44:05

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 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-25T21:46:47', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'ec02de19-eba3-4412-9d56-483b934ccaf7'	System	26 Aug 2020 04:46:53
User entered 'None (1)'	System	26 Aug 2020 04:46:53

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:44:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-25T21:46:50', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'ec02de19-eba3-4412-9d56-483b934ccaf7'	System	26 Aug 2020 04:46:53
User entered '25 Aug 2020 21:46'	System	26 Aug 2020 04:46:53

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:44:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:44:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
Data entry locked.	System	19 Aug 2020 18:42:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:44:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-19T11:54:18', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '31f47e3a-44d6-44ee-88a4-7630138ae5b5'	System	19 Aug 2020 18:54:49
User entered 'None (0)'	System	19 Aug 2020 18:54:49

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:44:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-19T11:54:23', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '31f47e3a-44d6-44ee-88a4-7630138ae5b5'	System	19 Aug 2020 18:54:49
User entered 'None (0)'	System	19 Aug 2020 18:54:49

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:44:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-19T11:54:26', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '31f47e3a-44d6-44ee-88a4-7630138ae5b5'	System	19 Aug 2020 18:54:49
User entered 'None (0)'	System	19 Aug 2020 18:54:49

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:44:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-19T11:54:29', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '31f47e3a-44d6-44ee-88a4-7630138ae5b5'	System	19 Aug 2020 18:54:49
User entered 'None (0)'	System	19 Aug 2020 18:54:49

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:44:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-19T11:54:31', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '31f47e3a-44d6-44ee-88a4-7630138ae5b5'	System	19 Aug 2020 18:54:49
User entered 'None (0)'	System	19 Aug 2020 18:54:49

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:44:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-19T11:54:34', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '31f47e3a-44d6-44ee-88a4-7630138ae5b5'	System	19 Aug 2020 18:54:49
User entered 'None (0)'	System	19 Aug 2020 18:54:49

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:44:05

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 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-19T11:54:41', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '31f47e3a-44d6-44ee-88a4-7630138ae5b5'	System	19 Aug 2020 18:54:49
User entered 'No (N)'	System	19 Aug 2020 18:54:49

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:44:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-19T11:54:46', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '31f47e3a-44d6-44ee-88a4-7630138ae5b5'	System	19 Aug 2020 18:54:49
User entered '19 Aug 2020 11:54'	System	19 Aug 2020 18:54:49

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:44:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '19 Aug 2020 11:41'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:44:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '19 Aug 2020 14:11'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
Data entry locked.	System	19 Aug 2020 18:42:58
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-19T22:07:46', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'e50fb1e6-24a7-4804-8710-39b5ffbca65d'	System	20 Aug 2020 05:08:23
User entered 'None (0)'	System	20 Aug 2020 05:08:23

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-19T22:07:55', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'e50fb1e6-24a7-4804-8710-39b5ffbca65d'	System	20 Aug 2020 05:08:23
User entered 'None (0)'	System	20 Aug 2020 05:08:23

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-19T22:08:00', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'e50fb1e6-24a7-4804-8710-39b5ffbca65d'	System	20 Aug 2020 05:08:23
User entered 'None (0)'	System	20 Aug 2020 05:08:23

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-19T22:08:03', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'e50fb1e6-24a7-4804-8710-39b5ffbca65d'	System	20 Aug 2020 05:08:23
User entered 'None (0)'	System	20 Aug 2020 05:08:23

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-19T22:08:06', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'e50fb1e6-24a7-4804-8710-39b5ffbca65d'	System	20 Aug 2020 05:08:23
User entered 'None (0)'	System	20 Aug 2020 05:08:23

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-19T22:08:08', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'e50fb1e6-24a7-4804-8710-39b5ffbca65d'	System	20 Aug 2020 05:08:23
User entered 'None (0)'	System	20 Aug 2020 05:08:23

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

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 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-19T22:08:16', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'e50fb1e6-24a7-4804-8710-39b5ffbca65d'	System	20 Aug 2020 05:08:23
User entered 'No (N)'	System	20 Aug 2020 05:08:23

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-19T22:08:19', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'e50fb1e6-24a7-4804-8710-39b5ffbca65d'	System	20 Aug 2020 05:08:23
User entered '19 Aug 2020 22:08'	System	20 Aug 2020 05:08:23

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '19 Aug 2020 15:06'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
Data entry locked.	System	19 Aug 2020 18:42:58
User entered 'Day 2'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:44:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-20T22:30:59', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'a0bb52db-2483-44ba-aa64-481f7e3777ac'	System	21 Aug 2020 05:31:43
User entered 'None (0)'	System	21 Aug 2020 05:31:43

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:44:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-20T22:31:04', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'a0bb52db-2483-44ba-aa64-481f7e3777ac'	System	21 Aug 2020 05:31:43
User entered 'Some interference with activity (2)'	System	21 Aug 2020 05:31:43

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:44:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-20T22:31:13', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'a0bb52db-2483-44ba-aa64-481f7e3777ac'	System	21 Aug 2020 05:31:43
User entered 'None (0)'	System	21 Aug 2020 05:31:43

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:44:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-20T22:31:16', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'a0bb52db-2483-44ba-aa64-481f7e3777ac'	System	21 Aug 2020 05:31:43
User entered 'None (0)'	System	21 Aug 2020 05:31:43

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:44:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-20T22:31:20', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'a0bb52db-2483-44ba-aa64-481f7e3777ac'	System	21 Aug 2020 05:31:43
User entered 'None (0)'	System	21 Aug 2020 05:31:43

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:44:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-20T22:31:22', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'a0bb52db-2483-44ba-aa64-481f7e3777ac'	System	21 Aug 2020 05:31:43
User entered 'None (0)'	System	21 Aug 2020 05:31:43

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:44:05

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 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-20T22:31:31', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'a0bb52db-2483-44ba-aa64-481f7e3777ac'	System	21 Aug 2020 05:31:43
User entered 'No (N)'	System	21 Aug 2020 05:31:43

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:44:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-20T22:31:41', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'a0bb52db-2483-44ba-aa64-481f7e3777ac'	System	21 Aug 2020 05:31:43
User entered '20 Aug 2020 22:31'	System	21 Aug 2020 05:31:43

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:44:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:44:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
Data entry locked.	System	19 Aug 2020 18:42:58
User entered 'Day 3'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:44:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-21T23:59:07', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '0977ff4a-63a1-4123-aa63-ce441c9763d5'	System	22 Aug 2020 06:59:25
User entered 'None (0)'	System	22 Aug 2020 06:59:25

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:44:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-21T23:59:09', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '0977ff4a-63a1-4123-aa63-ce441c9763d5'	System	22 Aug 2020 06:59:25
User entered 'None (0)'	System	22 Aug 2020 06:59:25

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:44:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-21T23:59:11', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '0977ff4a-63a1-4123-aa63-ce441c9763d5'	System	22 Aug 2020 06:59:25
User entered 'None (0)'	System	22 Aug 2020 06:59:25

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:44:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-21T23:59:14', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '0977ff4a-63a1-4123-aa63-ce441c9763d5'	System	22 Aug 2020 06:59:25
User entered 'None (0)'	System	22 Aug 2020 06:59:25

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:44:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-21T23:59:16', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '0977ff4a-63a1-4123-aa63-ce441c9763d5'	System	22 Aug 2020 06:59:25
User entered 'None (0)'	System	22 Aug 2020 06:59:25

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:44:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-21T23:59:17', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '0977ff4a-63a1-4123-aa63-ce441c9763d5'	System	22 Aug 2020 06:59:25
User entered 'None (0)'	System	22 Aug 2020 06:59:25

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:44:05

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 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-21T23:59:21', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '0977ff4a-63a1-4123-aa63-ce441c9763d5'	System	22 Aug 2020 06:59:25
User entered 'No (N)'	System	22 Aug 2020 06:59:25

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:44:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-21T23:59:24', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '0977ff4a-63a1-4123-aa63-ce441c9763d5'	System	22 Aug 2020 06:59:25
User entered '21 Aug 2020 23:59'	System	22 Aug 2020 06:59:25

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:44:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:44:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
Data entry locked.	System	19 Aug 2020 18:42:58
User entered 'Day 4'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:44:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-22T22:42:35', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '9d7ebb3b-6ee1-4c17-8c34-fee5a5732374'	System	23 Aug 2020 05:43:17
User entered 'None (0)'	System	23 Aug 2020 05:43:17

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:44:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-22T22:42:43', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '9d7ebb3b-6ee1-4c17-8c34-fee5a5732374'	System	23 Aug 2020 05:43:17
User entered 'Some interference with activity (2)'	System	23 Aug 2020 05:43:17

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:44:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-22T22:42:45', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '9d7ebb3b-6ee1-4c17-8c34-fee5a5732374'	System	23 Aug 2020 05:43:17
User entered 'None (0)'	System	23 Aug 2020 05:43:17

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:44:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-22T22:42:47', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '9d7ebb3b-6ee1-4c17-8c34-fee5a5732374'	System	23 Aug 2020 05:43:17
User entered 'None (0)'	System	23 Aug 2020 05:43:17

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:44:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-22T22:42:49', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '9d7ebb3b-6ee1-4c17-8c34-fee5a5732374'	System	23 Aug 2020 05:43:17
User entered 'None (0)'	System	23 Aug 2020 05:43:17

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:44:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-22T22:42:51', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '9d7ebb3b-6ee1-4c17-8c34-fee5a5732374'	System	23 Aug 2020 05:43:17
User entered 'None (0)'	System	23 Aug 2020 05:43:17

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:44:05

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 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-22T22:42:56', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '9d7ebb3b-6ee1-4c17-8c34-fee5a5732374'	System	23 Aug 2020 05:43:17
User entered 'No (N)'	System	23 Aug 2020 05:43:17

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:44:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-22T22:43:14', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '9d7ebb3b-6ee1-4c17-8c34-fee5a5732374'	System	23 Aug 2020 05:43:17
User entered '22 Aug 2020 22:43'	System	23 Aug 2020 05:43:17

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:44:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:44:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
Data entry locked.	System	19 Aug 2020 18:42:58
User entered 'Day 5'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:44:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-24T00:00:43', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '6a2e7271-2cc5-4c7f-b737-9d65e8a96cff'	System	24 Aug 2020 07:01:03
User entered 'None (0)'	System	24 Aug 2020 07:01:03

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:44:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-24T00:00:45', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '6a2e7271-2cc5-4c7f-b737-9d65e8a96cff'	System	24 Aug 2020 07:01:03
User entered 'None (0)'	System	24 Aug 2020 07:01:03

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:44:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-24T00:00:47', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '6a2e7271-2cc5-4c7f-b737-9d65e8a96cff'	System	24 Aug 2020 07:01:03
User entered 'None (0)'	System	24 Aug 2020 07:01:03

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:44:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-24T00:00:49', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '6a2e7271-2cc5-4c7f-b737-9d65e8a96cff'	System	24 Aug 2020 07:01:03
User entered 'None (0)'	System	24 Aug 2020 07:01:03

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:44:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-24T00:00:50', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '6a2e7271-2cc5-4c7f-b737-9d65e8a96cff'	System	24 Aug 2020 07:01:03
User entered 'None (0)'	System	24 Aug 2020 07:01:03

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:44:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-24T00:00:52', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '6a2e7271-2cc5-4c7f-b737-9d65e8a96cff'	System	24 Aug 2020 07:01:03
User entered 'None (0)'	System	24 Aug 2020 07:01:03

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:44:05

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 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-24T00:00:55', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '6a2e7271-2cc5-4c7f-b737-9d65e8a96cff'	System	24 Aug 2020 07:01:03
User entered 'No (N)'	System	24 Aug 2020 07:01:03

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:44:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-24T00:01:00', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '6a2e7271-2cc5-4c7f-b737-9d65e8a96cff'	System	24 Aug 2020 07:01:03
User entered '24 Aug 2020 00:01'	System	24 Aug 2020 07:01:03

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:44:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:44:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
Data entry locked.	System	19 Aug 2020 18:42:58
User entered 'Day 6'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:44:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-25T00:01:12', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '58c550a0-dbe0-437e-be90-301a8b94ed4d'	System	25 Aug 2020 07:01:33
User entered 'None (0)'	System	25 Aug 2020 07:01:33

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:44:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-25T00:01:19', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '58c550a0-dbe0-437e-be90-301a8b94ed4d'	System	25 Aug 2020 07:01:33
User entered 'Some interference with activity (2)'	System	25 Aug 2020 07:01:33

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:44:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-25T00:01:21', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '58c550a0-dbe0-437e-be90-301a8b94ed4d'	System	25 Aug 2020 07:01:33
User entered 'None (0)'	System	25 Aug 2020 07:01:33

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:44:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-25T00:01:23', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '58c550a0-dbe0-437e-be90-301a8b94ed4d'	System	25 Aug 2020 07:01:33
User entered 'None (0)'	System	25 Aug 2020 07:01:33

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:44:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-25T00:01:24', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '58c550a0-dbe0-437e-be90-301a8b94ed4d'	System	25 Aug 2020 07:01:33
User entered 'None (0)'	System	25 Aug 2020 07:01:33

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:44:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-25T00:01:26', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '58c550a0-dbe0-437e-be90-301a8b94ed4d'	System	25 Aug 2020 07:01:33
User entered 'None (0)'	System	25 Aug 2020 07:01:33

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:44:05

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 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-25T00:01:28', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '58c550a0-dbe0-437e-be90-301a8b94ed4d'	System	25 Aug 2020 07:01:33
User entered 'No (N)'	System	25 Aug 2020 07:01:33

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:44:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-25T00:01:31', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '58c550a0-dbe0-437e-be90-301a8b94ed4d'	System	25 Aug 2020 07:01:33
User entered '25 Aug 2020 00:01'	System	25 Aug 2020 07:01:33

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:44:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:44:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
Data entry locked.	System	19 Aug 2020 18:42:58
User entered 'Day 7'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:44:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-25T21:46:54', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'b6d7c811-e91d-4981-a844-7c49cdb68f52'	System	26 Aug 2020 04:47:16
User entered 'None (0)'	System	26 Aug 2020 04:47:16

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:44:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-25T21:46:58', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'b6d7c811-e91d-4981-a844-7c49cdb68f52'	System	26 Aug 2020 04:47:16
User entered 'None (0)'	System	26 Aug 2020 04:47:16

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:44:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-25T21:47:00', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'b6d7c811-e91d-4981-a844-7c49cdb68f52'	System	26 Aug 2020 04:47:16
User entered 'None (0)'	System	26 Aug 2020 04:47:16

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:44:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-25T21:47:01', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'b6d7c811-e91d-4981-a844-7c49cdb68f52'	System	26 Aug 2020 04:47:16
User entered 'None (0)'	System	26 Aug 2020 04:47:16

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:44:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-25T21:47:03', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'b6d7c811-e91d-4981-a844-7c49cdb68f52'	System	26 Aug 2020 04:47:16
User entered 'None (0)'	System	26 Aug 2020 04:47:16

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:44:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-25T21:47:05', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'b6d7c811-e91d-4981-a844-7c49cdb68f52'	System	26 Aug 2020 04:47:16
User entered 'None (0)'	System	26 Aug 2020 04:47:16

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:44:05

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 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-25T21:47:08', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'b6d7c811-e91d-4981-a844-7c49cdb68f52'	System	26 Aug 2020 04:47:16
User entered 'No (N)'	System	26 Aug 2020 04:47:16

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:44:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-08-25T21:47:10', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'b6d7c811-e91d-4981-a844-7c49cdb68f52'	System	26 Aug 2020 04:47:16
User entered '25 Aug 2020 21:47'	System	26 Aug 2020 04:47:16

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:44:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 18:42:58

US3462244

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:44:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 18:42:58

US3462244

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:37
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	16 Sep 2020 19:17:17

US3462244

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:05

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:37
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '26 Aug 2020'	(b) (4) Danuel Hamlin (b) (4)	16 Sep 2020 19:17:17

US3462244

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:37
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danuel Hamlin (b) (4)	16 Sep 2020 19:17:17

US3462244

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:37
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	16 Sep 2020 19:17:17

US3462244

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:37
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	16 Sep 2020 19:17:24

US3462244

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:37
User entered 'I'	System	16 Sep 2020 19:17:24

US3462244

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:37
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	16 Sep 2020 19:17:50

US3462244

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:37
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '02 Sep 2020'	(b) (4) Danuel Hamlin (b) (4)	16 Sep 2020 19:17:50

US3462244

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:37
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danuel Hamlin (b) (4)	16 Sep 2020 19:17:50

US3462244

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:37
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	16 Sep 2020 19:17:50

US3462244

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:37
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	16 Sep 2020 19:17:57

US3462244

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:37
User entered 'I'	System	16 Sep 2020 19:17:57

US3462244

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:37
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	16 Sep 2020 19:18:11

US3462244

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:05

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:37
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '09 Sep 2020'	(b) (4) Danuel Hamlin (b) (4)	16 Sep 2020 19:18:11

US3462244

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:37
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danuel Hamlin (b) (4)	16 Sep 2020 19:18:11

US3462244

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:37
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	16 Sep 2020 19:18:11

US3462244

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:37
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	16 Sep 2020 19:18:19

US3462244

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:37
User entered 'I'	System	16 Sep 2020 19:18:19

US3462244

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:40:12
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 14OCT2020 is reported under Visit 3 Day 57 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)	04 Nov 2020 08:41:38
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 14OCT2020 is reported under Visit 3 Day 57 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 'Added' (Site from DM).	Danuel Hamlin (b) (4)	04 Nov 2020 00:52:01
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 14OCT2020 is reported under Visit 3 Day 57 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 Nov 2020 08:45:21
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	16 Sep 2020 19:18:34

US3462244

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:40:12
User entered '16 Sep 2020'	(b) (4) Danuel Hamlin (b) (4)	16 Sep 2020 19:18:34

US3462244

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:40:12
User entered 'Clinic (Clinic)'	(b) (4) Danuel Hamlin (b) (4)	16 Sep 2020 19:18:34

US3462244

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User entered 'VISIT2'	System	16 Sep 2020 19:18:34

US3462244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User accepted default value 'Pre-Dose (PREDOSE)'	Danuel Hamlin (b) (4)	24 Sep 2020 20:43:55

US3462244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:40:12
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 20:43:55

US3462244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:40:12
User entered '16 Sep 2020'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 20:43:55

US3462244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:40:12
User entered '11:18'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 20:43:55

US3462244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User entered '16 Sep 2020 11:18'	System	24 Sep 2020 20:43:55

US3462244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:40:12
User entered '97.5' F	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 20:43:55

US3462244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:40:12
User entered 'Other (Other)'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 20:43:55

US3462244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:40:12
User entered 'TYMPANIC'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 20:43:55

US3462244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:40:12
User entered '70'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 20:43:55

US3462244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User entered 'bpm'	System	24 Sep 2020 20:43:55

US3462244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:40:12
User entered '18'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 20:43:55

US3462244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User entered 'breaths/min'	System	24 Sep 2020 20:43:55

US3462244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:40:12
User entered '97'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 20:43:55

US3462244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User entered 'mmHg'	System	24 Sep 2020 20:43:55

US3462244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:40:12
User closed query 'Per CDM: Thank you for your response. However, please indicate if value is CS/NCS.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 07:31:31
Query 'Per CDM: Thank you for your response. However, please indicate if value is CS/NCS.' answered with 'Value is NCS.' (Site from DM).		18 Nov 2020 21:53:36
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		05 Nov 2020 20:31:08
User opened query 'Per CDM: Thank you for your response. However, please indicate if value is CS/NCS.' (Site from DM).		05 Nov 2020 20:31:03
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Confirmed. Value is correct' (Site from System).	Danuel Hamlin (b) (4)	04 Nov 2020 00:54:12
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		24 Sep 2020 20:43:55
User entered '56'	Danuel Hamlin (b) (4)	24 Sep 2020 20:43:55

US3462244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:05

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User entered 'mmHg'	System	24 Sep 2020 20:43:55

US3462244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User accepted default value 'Post-Dose (POSTDOSE)'	Danuel Hamlin (b) (4)	24 Sep 2020 20:43:55

US3462244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:40:12
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 20:43:55

US3462244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:40:12
User entered '16 Sep 2020'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 20:43:55

US3462244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:40:12
User entered '12:21'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 20:43:55

US3462244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User entered '16 Sep 2020 12:21'	System	24 Sep 2020 20:43:55

US3462244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:40:12
User entered '97.8' F	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 20:43:55

US3462244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:40:12
User entered 'Other (Other)'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 20:43:55

US3462244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:40:12
User entered 'TYMPANIC'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 20:43:55

US3462244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:40:12
User entered '82'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 20:43:55

US3462244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User entered 'bpm'	System	24 Sep 2020 20:43:55

US3462244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:40:12
User entered '16'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 20:43:55

US3462244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User entered 'breaths/min'	System	24 Sep 2020 20:43:55

US3462244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:40:12
User entered '104'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 20:43:55

US3462244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User entered 'mmHg'	System	24 Sep 2020 20:43:55

US3462244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:40:12
User entered '60'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 20:43:55

US3462244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User entered 'mmHg'	System	24 Sep 2020 20:43:55

US3462244

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:44:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:40:12
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 20:44:17

US3462244

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:44:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:40:12
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 20:44:17

US3462244

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:44:05

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:40:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Oct 2020 22:58:05

US3462244

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:44:05

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:40:12
User entered '16 Sep 2020'	(b) (4), (b) (6)	11 Oct 2020 22:58:05

US3462244

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:44:05

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:40:12
User entered 'Urine (URINE)'	(b) (4), (b) (6)	11 Oct 2020 22:58:05

US3462244

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:44:05

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:40:12
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	11 Oct 2020 22:58:05

US3462244

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:44:05

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:40:12
User entered 'No (N)'	(b) (4), (b) (6)	11 Oct 2020 22:58:05

US3462244

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:44:05

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:40:12
User entered empty.	(b) (4), (b) (6)	11 Oct 2020 22:58:05

US3462244

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:44:05

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:40:12
User entered empty.	(b) (4), (b) (6)	11 Oct 2020 22:58:05

US3462244

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:44:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User entered empty.	System	11 Oct 2020 22:58:05

US3462244

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:05

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	16 Sep 2020 19:18:57

US3462244

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:05

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	16 Sep 2020 19:18:57

US3462244

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:05

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 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered empty.	Danuel Hamlin (b) (4)	16 Sep 2020 19:18:57

US3462244

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:05

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User entered 'MRNA-1273 OR PLACEBO'	System	16 Sep 2020 19:18:57

US3462244

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:05

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '16 Sep 2020'	(b) (4) Danuel Hamlin (b) (4)	16 Sep 2020 19:18:57

US3462244

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:05

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '11:50'	(b) (4) Danuel Hamlin (b) (4)	16 Sep 2020 19:18:57

US3462244

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:05

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User entered '16 Sep 2020 11:50'	System	16 Sep 2020 19:18:57

US3462244

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:05

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'Left Arm (LEFT ARM)'	(b) (4) Danuel Hamlin (b) (4)	16 Sep 2020 19:18:57

US3462244

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:05

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User entered 'ONCE'	System	16 Sep 2020 19:18:57

US3462244

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:05

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User entered 'INTRAMUSCULAR'	System	16 Sep 2020 19:18:57

US3462244

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:44:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 20:44:38

US3462244

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:44:05

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '16 Sep 2020'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 20:44:38

US3462244

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:44:05

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '11:34'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 20:44:38

US3462244

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:44:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User entered '16 Sep 2020 11:34'	System	24 Sep 2020 20:44:38

US3462244

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:44:05

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '16 Sep 2020'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 20:44:59

US3462244

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:44:05

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Danuel Hamlin (b) (4)	24 Sep 2020 20:44:59

US3462244

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:44:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 20:44:59

US3462244

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:44:05

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '11:36'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 20:44:59

US3462244

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:44:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User entered '16 Sep 2020 11:36'	System	24 Sep 2020 20:44:59

US3462244

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:44:05

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Danuel Hamlin (b) (4)	24 Sep 2020 20:44:59

US3462244

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:44:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	11 Oct 2020 22:58:35
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	24 Sep 2020 20:44:59

US3462244

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:44:05

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	11 Oct 2020 22:58:35
User entered '11:36'	Danuel Hamlin (b) (4)	24 Sep 2020 20:44:59

US3462244

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:44:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User entered empty.	System	11 Oct 2020 22:58:35
User entered '16 Sep 2020 11:36'	System	24 Sep 2020 20:44:59

US3462244

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 20:45:05

US3462244

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User entered 'I'	System	24 Sep 2020 20:45:05

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
Data entry locked.	System	16 Sep 2020 19:18:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:44:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-16T12:20:13', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '538c6e0e-c88c-4783-b2bc-900f032fd923'	System	16 Sep 2020 19:20:47
User entered 'Yes (Y)'	System	16 Sep 2020 19:20:47

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:44:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-16T12:20:22', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '538c6e0e-c88c-4783-b2bc-900f032fd923'	System	16 Sep 2020 19:20:47
User entered '97.8'	System	16 Sep 2020 19:20:47

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-16T12:20:37', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '538c6e0e-c88c-4783-b2bc-900f032fd923'	System	16 Sep 2020 19:20:47
User entered 'No (N)'	System	16 Sep 2020 19:20:47

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:44:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-16T12:20:45', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '538c6e0e-c88c-4783-b2bc-900f032fd923'	System	16 Sep 2020 19:20:47
User entered '16 Sep 2020 12:20'	System	16 Sep 2020 19:20:47

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:44:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '16 Sep 2020 12:10'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:44:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '16 Sep 2020 14:40'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
Data entry locked.	System	16 Sep 2020 19:18:57
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-16T20:58:15', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'c683a301-7f48-44b5-b2d5-161a57fc72fd'	System	17 Sep 2020 03:58:38
User entered 'Yes (Y)'	System	17 Sep 2020 03:58:38

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-16T20:58:19', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'c683a301-7f48-44b5-b2d5-161a57fc72fd'	System	17 Sep 2020 03:58:38
User entered '99.3'	System	17 Sep 2020 03:58:38

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-16T20:58:22', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'c683a301-7f48-44b5-b2d5-161a57fc72fd'	System	17 Sep 2020 03:58:38
User entered 'Yes (Y)'	System	17 Sep 2020 03:58:38

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Added' (Site from System).		12 Nov 2020 20:23:56
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Danuel Hamlin (b) (4)	04 Nov 2020 00:13:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-16T20:58:29', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'c683a301-7f48-44b5-b2d5-161a57fc72fd'		
User entered '1'	System	17 Sep 2020 03:58:38

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-16T20:58:29', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'c683a301-7f48-44b5-b2d5-161a57fc72fd'	System	17 Sep 2020 03:58:38
User entered '0'	System	17 Sep 2020 03:58:38

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-16T20:58:35', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'c683a301-7f48-44b5-b2d5-161a57fc72fd'	System	17 Sep 2020 03:58:38
User entered '16 Sep 2020 20:58'	System	17 Sep 2020 03:58:38

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '16 Sep 2020 15:35'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
Data entry locked.	System	16 Sep 2020 19:18:57
User entered 'Day 2'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:44:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-17T22:32:47', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '430cade0-51bd-4ef4-935b-a6016495bed8'	System	18 Sep 2020 05:33:27
User entered 'Yes (Y)'	System	18 Sep 2020 05:33:27

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:44:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-17T22:32:50', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '430cade0-51bd-4ef4-935b-a6016495bed8'	System	18 Sep 2020 05:33:27
User entered '98.3'	System	18 Sep 2020 05:33:27

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-17T22:32:54', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '430cade0-51bd-4ef4-935b-a6016495bed8'	System	18 Sep 2020 05:33:27
User entered 'Yes (Y)'	System	18 Sep 2020 05:33:27

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Added' (Site from System).		12 Nov 2020 20:24:03
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-17T22:33:09', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '430cade0-51bd-4ef4-935b-a6016495bed8'	Danuel Hamlin (b) (4)	04 Nov 2020 00:23:11
User entered '1'	System	18 Sep 2020 05:33:27
	System	18 Sep 2020 05:33:27
	System	18 Sep 2020 05:33:27

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:44:05

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-17T22:33:09', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '430cade0-51bd-4ef4-935b-a6016495bed8'	System	18 Sep 2020 05:33:27
User entered '0'	System	18 Sep 2020 05:33:27

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:44:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-17T22:33:24', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '430cade0-51bd-4ef4-935b-a6016495bed8'	System	18 Sep 2020 05:33:27
User entered '17 Sep 2020 22:33'	System	18 Sep 2020 05:33:27

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:44:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:44:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
Data entry locked.	System	16 Sep 2020 19:18:57
User entered 'Day 3'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:44:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-18T22:03:50', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '339d8181-c1f0-451b-8aae-42c947896578'	System	19 Sep 2020 05:04:13
User entered 'Yes (Y)'	System	19 Sep 2020 05:04:13

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:44:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-18T22:03:58', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '339d8181-c1f0-451b-8aae-42c947896578'	System	19 Sep 2020 05:04:13
User entered '98.2'	System	19 Sep 2020 05:04:13

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-18T22:04:04', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '339d8181-c1f0-451b-8aae-42c947896578'	System	19 Sep 2020 05:04:13
User entered 'No (N)'	System	19 Sep 2020 05:04:13

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:44:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-18T22:04:09', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '339d8181-c1f0-451b-8aae-42c947896578'	System	19 Sep 2020 05:04:13
User entered '18 Sep 2020 22:04'	System	19 Sep 2020 05:04:13

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:44:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:44:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
Data entry locked.	System	16 Sep 2020 19:18:57
User entered 'Day 4'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:44:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-19T22:26:53', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '46c5e1a4-a543-4b90-8ad3-fa60fc822363'	System	20 Sep 2020 05:27:12
User entered 'Yes (Y)'	System	20 Sep 2020 05:27:12

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:44:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-19T22:26:58', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '46c5e1a4-a543-4b90-8ad3-fa60fc822363'	System	20 Sep 2020 05:27:12
User entered '99.0'	System	20 Sep 2020 05:27:12

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-19T22:27:04', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '46c5e1a4-a543-4b90-8ad3-fa60fc822363'	System	20 Sep 2020 05:27:12
User entered 'No (N)'	System	20 Sep 2020 05:27:12

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:44:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-19T22:27:07', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '46c5e1a4-a543-4b90-8ad3-fa60fc822363'	System	20 Sep 2020 05:27:12
User entered '19 Sep 2020 22:27'	System	20 Sep 2020 05:27:12

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:44:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:44:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
Data entry locked.	System	16 Sep 2020 19:18:57
User entered 'Day 5'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:44:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-20T22:21:44', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'fe74d0a3-048f-4d16-b8a9-8c4c361c90a0'	System	21 Sep 2020 05:22:05
User entered 'Yes (Y)'	System	21 Sep 2020 05:22:05

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:44:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-20T22:21:49', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'fe74d0a3-048f-4d16-b8a9-8c4c361c90a0'	System	21 Sep 2020 05:22:05
User entered '98.8'	System	21 Sep 2020 05:22:05

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-20T22:21:54', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'fe74d0a3-048f-4d16-b8a9-8c4c361c90a0'	System	21 Sep 2020 05:22:05
User entered 'No (N)'	System	21 Sep 2020 05:22:05

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:44:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-20T22:21:59', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'fe74d0a3-048f-4d16-b8a9-8c4c361c90a0'	System	21 Sep 2020 05:22:05
User entered '20 Sep 2020 22:21'	System	21 Sep 2020 05:22:05

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:44:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:44:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
Data entry locked.	System	16 Sep 2020 19:18:57
User entered 'Day 6'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:44:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-21T23:15:40', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '6b9d37b2-8da1-4182-99f1-a059ca4060e2'	System	22 Sep 2020 06:15:55
User entered 'Yes (Y)'	System	22 Sep 2020 06:15:55

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:44:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-21T23:15:44', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '6b9d37b2-8da1-4182-99f1-a059ca4060e2'	System	22 Sep 2020 06:15:55
User entered '99.1'	System	22 Sep 2020 06:15:55

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-21T23:15:47', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '6b9d37b2-8da1-4182-99f1-a059ca4060e2'	System	22 Sep 2020 06:15:55
User entered 'No (N)'	System	22 Sep 2020 06:15:55

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:44:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-21T23:15:51', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '6b9d37b2-8da1-4182-99f1-a059ca4060e2'	System	22 Sep 2020 06:15:55
User entered '21 Sep 2020 23:15'	System	22 Sep 2020 06:15:55

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:44:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:44:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
Data entry locked.	System	16 Sep 2020 19:18:57
User entered 'Day 7'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:44:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-22T23:21:13', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '573c6d09-11bc-423c-a195-4e9e7f4d9ece'	System	23 Sep 2020 06:21:27
User entered 'Yes (Y)'	System	23 Sep 2020 06:21:27

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:44:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-22T23:21:18', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '573c6d09-11bc-423c-a195-4e9e7f4d9ece'	System	23 Sep 2020 06:21:27
User entered '98.1'	System	23 Sep 2020 06:21:27

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-22T23:21:20', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '573c6d09-11bc-423c-a195-4e9e7f4d9ece'	System	23 Sep 2020 06:21:27
User entered 'No (N)'	System	23 Sep 2020 06:21:27

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:44:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-22T23:21:25', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '573c6d09-11bc-423c-a195-4e9e7f4d9ece'	System	23 Sep 2020 06:21:27
User entered '22 Sep 2020 23:21'	System	23 Sep 2020 06:21:27

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:44:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:44:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
Data entry locked.	System	16 Sep 2020 19:18:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:44:05

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 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-16T12:21:02', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '448f6560-986b-4016-b944-b85fd6b6aecb'	System	16 Sep 2020 19:21:42
User entered 'Does not interfere with activity (2)'	System	16 Sep 2020 19:21:42

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-16T12:21:19', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '448f6560-986b-4016-b944-b85fd6b6aecb'	System	16 Sep 2020 19:21:42
User entered 'No (N)'	System	16 Sep 2020 19:21:42

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-16T12:21:25', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '448f6560-986b-4016-b944-b85fd6b6aecb'	System	16 Sep 2020 19:21:42
User entered 'No (N)'	System	16 Sep 2020 19:21:42

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:44:05

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 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-16T12:21:35', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '448f6560-986b-4016-b944-b85fd6b6aecb'	System	16 Sep 2020 19:21:42
User entered 'None (1)'	System	16 Sep 2020 19:21:42

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:44:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-16T12:21:39', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '448f6560-986b-4016-b944-b85fd6b6aecb'	System	16 Sep 2020 19:21:42
User entered '16 Sep 2020 12:21'	System	16 Sep 2020 19:21:42

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:44:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '16 Sep 2020 12:10'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:44:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '16 Sep 2020 14:40'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
Data entry locked.	System	16 Sep 2020 19:18:57
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

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 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-16T20:58:47', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '715c1517-bd20-4947-bc2e-12c7004cbbbf'	System	17 Sep 2020 04:00:41
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	17 Sep 2020 04:00:41

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-16T20:59:03', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '715c1517-bd20-4947-bc2e-12c7004cbbbf'	System	17 Sep 2020 04:00:41
User entered 'No (N)'	System	17 Sep 2020 04:00:41

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-16T20:59:19', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '715c1517-bd20-4947-bc2e-12c7004cbbbf'	System	17 Sep 2020 04:00:41
User entered 'No (N)'	System	17 Sep 2020 04:00:41

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

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 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-16T20:59:54', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '715c1517-bd20-4947-bc2e-12c7004cbbbf'	System	17 Sep 2020 04:00:41
User entered 'None (1)'	System	17 Sep 2020 04:00:41

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-16T21:00:39', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '715c1517-bd20-4947-bc2e-12c7004cbbbf'	System	17 Sep 2020 04:00:41
User entered '16 Sep 2020 21:00'	System	17 Sep 2020 04:00:41

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '16 Sep 2020 15:35'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
Data entry locked.	System	16 Sep 2020 19:18:57
User entered 'Day 2'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:44:05

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 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-17T22:33:46', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '917febf8-7625-4471-8cb2-cca7625786ae'	System	18 Sep 2020 05:34:49
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	18 Sep 2020 05:34:49

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-17T22:33:57', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '917febf8-7625-4471-8cb2-cca7625786ae'	System	18 Sep 2020 05:34:49
User entered 'No (N)'	System	18 Sep 2020 05:34:49

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-17T22:34:05', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '917febf8-7625-4471-8cb2-cca7625786ae'	System	18 Sep 2020 05:34:49
User entered 'No (N)'	System	18 Sep 2020 05:34:49

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:44:05

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 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-17T22:34:33', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '917febf8-7625-4471-8cb2-cca7625786ae'	System	18 Sep 2020 05:34:49
User entered 'None (1)'	System	18 Sep 2020 05:34:49

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:44:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-17T22:34:45', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '917febf8-7625-4471-8cb2-cca7625786ae'	System	18 Sep 2020 05:34:49
User entered '17 Sep 2020 22:34'	System	18 Sep 2020 05:34:49

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:44:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:44:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
Data entry locked.	System	16 Sep 2020 19:18:57
User entered 'Day 3'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:44:05

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 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-18T21:53:57', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '0d656eba-5aca-48fd-acd7-7a8b70fe0b93'	System	19 Sep 2020 04:54:38
User entered 'Does not interfere with activity (2)'	System	19 Sep 2020 04:54:38

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-18T21:54:05', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '0d656eba-5aca-48fd-acd7-7a8b70fe0b93'	System	19 Sep 2020 04:54:38
User entered 'No (N)'	System	19 Sep 2020 04:54:38

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-18T21:54:10', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '0d656eba-5aca-48fd-acd7-7a8b70fe0b93'	System	19 Sep 2020 04:54:38
User entered 'No (N)'	System	19 Sep 2020 04:54:38

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:44:05

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 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-18T21:54:29', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '0d656eba-5aca-48fd-acd7-7a8b70fe0b93'	System	19 Sep 2020 04:54:38
User entered 'Does not interfere with activity (2)'	System	19 Sep 2020 04:54:38

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:44:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-18T21:54:35', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '0d656eba-5aca-48fd-acd7-7a8b70fe0b93'	System	19 Sep 2020 04:54:38
User entered '18 Sep 2020 21:54'	System	19 Sep 2020 04:54:38

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:44:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:44:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
Data entry locked.	System	16 Sep 2020 19:18:57
User entered 'Day 4'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:44:05

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 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-19T22:27:26', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'd7d4070c-71df-4c7f-9a6a-e72984d2e525'	System	20 Sep 2020 05:27:53
User entered 'Does not interfere with activity (2)'	System	20 Sep 2020 05:27:53

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-19T22:27:31', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'd7d4070c-71df-4c7f-9a6a-e72984d2e525'	System	20 Sep 2020 05:27:53
User entered 'No (N)'	System	20 Sep 2020 05:27:53

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-19T22:27:33', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'd7d4070c-71df-4c7f-9a6a-e72984d2e525'	System	20 Sep 2020 05:27:53
User entered 'No (N)'	System	20 Sep 2020 05:27:53

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:44:05

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 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-19T22:27:43', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'd7d4070c-71df-4c7f-9a6a-e72984d2e525'	System	20 Sep 2020 05:27:53
User entered 'Does not interfere with activity (2)'	System	20 Sep 2020 05:27:53

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:44:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-19T22:27:48', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'd7d4070c-71df-4c7f-9a6a-e72984d2e525'	System	20 Sep 2020 05:27:53
User entered '19 Sep 2020 22:27'	System	20 Sep 2020 05:27:53

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:44:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:44:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
Data entry locked.	System	16 Sep 2020 19:18:57
User entered 'Day 5'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:44:05

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 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-20T22:22:26', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'b8b4599a-3ab1-4a1b-b346-6516c9cc6b6a'	System	21 Sep 2020 05:22:52
User entered 'None (1)'	System	21 Sep 2020 05:22:52

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-20T22:22:33', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'b8b4599a-3ab1-4a1b-b346-6516c9cc6b6a'	System	21 Sep 2020 05:22:52
User entered 'No (N)'	System	21 Sep 2020 05:22:52

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-20T22:22:39', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'b8b4599a-3ab1-4a1b-b346-6516c9cc6b6a'		21 Sep 2020 05:22:52
User entered 'No (N)'	System	21 Sep 2020 05:22:52

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:44:05

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 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-20T22:22:43', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'b8b4599a-3ab1-4a1b-b346-6516c9cc6b6a'	System	21 Sep 2020 05:22:52
User entered 'None (1)'	System	21 Sep 2020 05:22:52

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:44:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-20T22:22:46', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'b8b4599a-3ab1-4a1b-b346-6516c9cc6b6a'	System	21 Sep 2020 05:22:52
User entered '20 Sep 2020 22:22'	System	21 Sep 2020 05:22:52

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:44:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:44:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '21 Sep 2020 11:59'		16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
Data entry locked.	System	16 Sep 2020 19:18:57
User entered 'Day 6'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:44:05

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 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-21T23:16:00', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'cad331e7-0e80-4e31-add4-c6530d177b26'	System	22 Sep 2020 06:16:17
User entered 'None (1)'	System	22 Sep 2020 06:16:17

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:44:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-21T23:16:05', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'cad331e7-0e80-4e31-add4-c6530d177b26'	System	22 Sep 2020 06:16:17
User entered 'No (N)'	System	22 Sep 2020 06:16:17

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-21T23:16:09', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'cad331e7-0e80-4e31-add4-c6530d177b26'	System	22 Sep 2020 06:16:17
User entered 'No (N)'	System	22 Sep 2020 06:16:17

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:44:05

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 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-21T23:16:12', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'cad331e7-0e80-4e31-add4-c6530d177b26'	System	22 Sep 2020 06:16:17
User entered 'None (1)'	System	22 Sep 2020 06:16:17

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:44:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-21T23:16:15', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'cad331e7-0e80-4e31-add4-c6530d177b26'	System	22 Sep 2020 06:16:17
User entered '21 Sep 2020 23:16'	System	22 Sep 2020 06:16:17

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:44:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '21 Sep 2020 12:00'		16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:44:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
Data entry locked.	System	16 Sep 2020 19:18:57
User entered 'Day 7'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:44:05

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 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-22T23:17:03', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'de65dd9e-94c5-4265-b2bc-33fd9e3f6009'	System	23 Sep 2020 06:17:20
User entered 'None (1)'	System	23 Sep 2020 06:17:20

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-22T23:17:08', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'de65dd9e-94c5-4265-b2bc-33fd9e3f6009'		23 Sep 2020 06:17:20
User entered 'No (N)'	System	23 Sep 2020 06:17:20

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-22T23:17:10', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'de65dd9e-94c5-4265-b2bc-33fd9e3f6009'	System	23 Sep 2020 06:17:20
User entered 'No (N)'	System	23 Sep 2020 06:17:20

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:44:05

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 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-22T23:17:13', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'de65dd9e-94c5-4265-b2bc-33fd9e3f6009'	System	23 Sep 2020 06:17:20
User entered 'None (1)'	System	23 Sep 2020 06:17:20

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:44:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-22T23:17:18', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'de65dd9e-94c5-4265-b2bc-33fd9e3f6009'	System	23 Sep 2020 06:17:20
User entered '22 Sep 2020 23:17'	System	23 Sep 2020 06:17:20

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:44:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '22 Sep 2020 12:00'		16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:44:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
Data entry locked.	System	16 Sep 2020 19:18:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:44:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-16T12:21:44', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'fe684b70-7dcf-4ba4-bc9e-64e0ebe4a760'	System	16 Sep 2020 19:22:05
User entered 'None (0)'	System	16 Sep 2020 19:22:05

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:44:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-16T12:21:46', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'fe684b70-7dcf-4ba4-bc9e-64e0ebe4a760'	System	16 Sep 2020 19:22:05
User entered 'None (0)'	System	16 Sep 2020 19:22:05

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:44:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-16T12:21:48', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'fe684b70-7dcf-4ba4-bc9e-64e0ebe4a760'	System	16 Sep 2020 19:22:05
User entered 'None (0)'	System	16 Sep 2020 19:22:05

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:44:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-16T12:21:50', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'fe684b70-7dcf-4ba4-bc9e-64e0ebe4a760'	System	16 Sep 2020 19:22:05
User entered 'None (0)'	System	16 Sep 2020 19:22:05

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:44:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-16T12:21:51', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'fe684b70-7dcf-4ba4-bc9e-64e0ebe4a760'	System	16 Sep 2020 19:22:05
User entered 'None (0)'	System	16 Sep 2020 19:22:05

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:44:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-16T12:21:53', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'fe684b70-7dcf-4ba4-bc9e-64e0ebe4a760'	System	16 Sep 2020 19:22:05
User entered 'None (0)'	System	16 Sep 2020 19:22:05

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:44:05

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 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-16T12:21:57', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'fe684b70-7dcf-4ba4-bc9e-64e0ebe4a760'		16 Sep 2020 19:22:05
User entered 'No (N)'	System	16 Sep 2020 19:22:05

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:44:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-16T12:21:59', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'fe684b70-7dcf-4ba4-bc9e-64e0ebe4a760'	System	16 Sep 2020 19:22:05
User entered '16 Sep 2020 12:21'	System	16 Sep 2020 19:22:05

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:44:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '16 Sep 2020 12:10'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:44:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '16 Sep 2020 14:40'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
Data entry locked.	System	16 Sep 2020 19:18:57
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-16T21:01:05', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'bcf909fb-5589-475e-a208-232891942c9f'	System	17 Sep 2020 04:02:55
User entered 'None (0)'	System	17 Sep 2020 04:02:55

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-16T21:01:32', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'bcf909fb-5589-475e-a208-232891942c9f'	System	17 Sep 2020 04:02:55
User entered 'No interference with activity (1)'	System	17 Sep 2020 04:02:55

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-16T21:02:14', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'bcf909fb-5589-475e-a208-232891942c9f'	System	17 Sep 2020 04:02:55
User entered 'Some interference with activity (2)'	System	17 Sep 2020 04:02:55

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-16T21:02:21', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'bcf909fb-5589-475e-a208-232891942c9f'	System	17 Sep 2020 04:02:55
User entered 'None (0)'	System	17 Sep 2020 04:02:55

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-16T21:02:24', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'bcf909fb-5589-475e-a208-232891942c9f'	System	17 Sep 2020 04:02:55
User entered 'None (0)'	System	17 Sep 2020 04:02:55

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-16T21:02:26', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'bcf909fb-5589-475e-a208-232891942c9f'		17 Sep 2020 04:02:55
User entered 'None (0)'	System	17 Sep 2020 04:02:55

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

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 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-16T21:02:45', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'bcf909fb-5589-475e-a208-232891942c9f'	System	17 Sep 2020 04:02:55
User entered 'No (N)'	System	17 Sep 2020 04:02:55

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-16T21:02:52', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'bcf909fb-5589-475e-a208-232891942c9f'	System	17 Sep 2020 04:02:55
User entered '16 Sep 2020 21:02'	System	17 Sep 2020 04:02:55

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '16 Sep 2020 15:35'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:44:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '17 Sep 2020 11:59'		16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
Data entry locked.	System	16 Sep 2020 19:18:57
User entered 'Day 2'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:44:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-17T22:34:56', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '48237efa-ab40-4362-a11a-1395e7999610'	System	18 Sep 2020 05:35:58
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	18 Sep 2020 05:35:58

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:44:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-17T22:35:05', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '48237efa-ab40-4362-a11a-1395e7999610'	System	18 Sep 2020 05:35:58
User entered 'Some interference with activity (2)'	System	18 Sep 2020 05:35:58

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:44:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-17T22:35:13', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '48237efa-ab40-4362-a11a-1395e7999610'	System	18 Sep 2020 05:35:58
User entered 'Significant; prevents daily activity (3)'	System	18 Sep 2020 05:35:58

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:44:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-17T22:35:17', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '48237efa-ab40-4362-a11a-1395e7999610'	System	18 Sep 2020 05:35:58
User entered 'None (0)'	System	18 Sep 2020 05:35:58

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:44:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-17T22:35:40', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '48237efa-ab40-4362-a11a-1395e7999610'	System	18 Sep 2020 05:35:58
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	18 Sep 2020 05:35:58

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:44:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-17T22:35:47', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '48237efa-ab40-4362-a11a-1395e7999610'		18 Sep 2020 05:35:58
User entered 'Some interference with activity not requiring medical attention (2)'	System	18 Sep 2020 05:35:58

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:44:05

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 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-17T22:35:52', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '48237efa-ab40-4362-a11a-1395e7999610'	System	18 Sep 2020 05:35:58
User entered 'No (N)'	System	18 Sep 2020 05:35:58

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:44:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-17T22:35:56', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '48237efa-ab40-4362-a11a-1395e7999610'	System	18 Sep 2020 05:35:58
User entered '17 Sep 2020 22:35'	System	18 Sep 2020 05:35:58

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:44:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:44:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
Data entry locked.	System	16 Sep 2020 19:18:57
User entered 'Day 3'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:44:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-18T21:52:58', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '4bb3a340-cf7a-45a7-9349-2cfd5c16d4b8'		19 Sep 2020 04:53:48
User entered 'No interference with activity (1)'	System	19 Sep 2020 04:53:48

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:44:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-18T21:53:08', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '4bb3a340-cf7a-45a7-9349-2cfd5c16d4b8'	System	19 Sep 2020 04:53:48
User entered 'Some interference with activity (2)'	System	19 Sep 2020 04:53:48

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:44:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-18T21:53:17', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '4bb3a340-cf7a-45a7-9349-2cfd5c16d4b8'	System	19 Sep 2020 04:53:48
User entered 'None (0)'	System	19 Sep 2020 04:53:48

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:44:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-18T21:53:21', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '4bb3a340-cf7a-45a7-9349-2cfd5c16d4b8'	System	19 Sep 2020 04:53:48
User entered 'None (0)'	System	19 Sep 2020 04:53:48

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:44:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-18T21:53:24', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '4bb3a340-cf7a-45a7-9349-2cfd5c16d4b8'	System	19 Sep 2020 04:53:48
User entered 'None (0)'	System	19 Sep 2020 04:53:48

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:44:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-18T21:53:27', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '4bb3a340-cf7a-45a7-9349-2cfd5c16d4b8'	System	19 Sep 2020 04:53:48
User entered 'None (0)'	System	19 Sep 2020 04:53:48

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:44:05

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 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-18T21:53:36', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '4bb3a340-cf7a-45a7-9349-2cfd5c16d4b8'	System	19 Sep 2020 04:53:48
User entered 'No (N)'	System	19 Sep 2020 04:53:48

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:44:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-18T21:53:41', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '4bb3a340-cf7a-45a7-9349-2cfd5c16d4b8'	System	19 Sep 2020 04:53:48
User entered '18 Sep 2020 21:53'	System	19 Sep 2020 04:53:48

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:44:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '18 Sep 2020 12:00'		16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:44:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '19 Sep 2020 11:59'		16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
Data entry locked.	System	16 Sep 2020 19:18:57
User entered 'Day 4'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:44:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-19T22:27:54', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '6f01e33d-5f49-48b7-b7c2-a6988769932e'	System	20 Sep 2020 05:28:26
User entered 'None (0)'	System	20 Sep 2020 05:28:26

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:44:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-19T22:28:00', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '6f01e33d-5f49-48b7-b7c2-a6988769932e'	System	20 Sep 2020 05:28:26
User entered 'Some interference with activity (2)'	System	20 Sep 2020 05:28:26

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:44:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-19T22:28:05', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '6f01e33d-5f49-48b7-b7c2-a6988769932e'	System	20 Sep 2020 05:28:26
User entered 'None (0)'	System	20 Sep 2020 05:28:26

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:44:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-19T22:28:09', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '6f01e33d-5f49-48b7-b7c2-a6988769932e'	System	20 Sep 2020 05:28:26
User entered 'None (0)'	System	20 Sep 2020 05:28:26

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:44:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-19T22:28:11', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '6f01e33d-5f49-48b7-b7c2-a6988769932e'	System	20 Sep 2020 05:28:26
User entered 'None (0)'	System	20 Sep 2020 05:28:26

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:44:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-19T22:28:13', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '6f01e33d-5f49-48b7-b7c2-a6988769932e'	System	20 Sep 2020 05:28:26
User entered 'None (0)'	System	20 Sep 2020 05:28:26

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:44:05

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 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-19T22:28:19', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '6f01e33d-5f49-48b7-b7c2-a6988769932e'	System	20 Sep 2020 05:28:26
User entered 'No (N)'	System	20 Sep 2020 05:28:26

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:44:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-19T22:28:23', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '6f01e33d-5f49-48b7-b7c2-a6988769932e'	System	20 Sep 2020 05:28:26
User entered '19 Sep 2020 22:28'	System	20 Sep 2020 05:28:26

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:44:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:44:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
Data entry locked.	System	16 Sep 2020 19:18:57
User entered 'Day 5'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:44:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-20T22:22:52', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '36c696db-0e07-40b0-9a9a-705cc97f61b7'	System	21 Sep 2020 05:23:18
User entered 'None (0)'	System	21 Sep 2020 05:23:18

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:44:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-20T22:22:55', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '36c696db-0e07-40b0-9a9a-705cc97f61b7'	System	21 Sep 2020 05:23:18
User entered 'None (0)'	System	21 Sep 2020 05:23:18

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:44:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-20T22:23:00', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '36c696db-0e07-40b0-9a9a-705cc97f61b7'	System	21 Sep 2020 05:23:18
User entered 'None (0)'	System	21 Sep 2020 05:23:18

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:44:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-20T22:23:03', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '36c696db-0e07-40b0-9a9a-705cc97f61b7'	System	21 Sep 2020 05:23:18
User entered 'None (0)'	System	21 Sep 2020 05:23:18

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:44:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-20T22:23:05', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '36c696db-0e07-40b0-9a9a-705cc97f61b7'	System	21 Sep 2020 05:23:18
User entered 'None (0)'	System	21 Sep 2020 05:23:18

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:44:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-20T22:23:08', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '36c696db-0e07-40b0-9a9a-705cc97f61b7'		21 Sep 2020 05:23:18
User entered 'None (0)'	System	21 Sep 2020 05:23:18

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:44:05

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 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-20T22:23:13', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '36c696db-0e07-40b0-9a9a-705cc97f61b7'	System	21 Sep 2020 05:23:18
User entered 'No (N)'	System	21 Sep 2020 05:23:18

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:44:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-20T22:23:16', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '36c696db-0e07-40b0-9a9a-705cc97f61b7'		21 Sep 2020 05:23:18
User entered '20 Sep 2020 22:23'	System	21 Sep 2020 05:23:18

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:44:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:44:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
Data entry locked.		16 Sep 2020 19:18:57
User entered 'Day 6'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:44:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-21T23:16:20', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '14ccdc78-c6a1-4eb9-98f3-e5e8f3072338'	System	22 Sep 2020 06:16:41
User entered 'None (0)'	System	22 Sep 2020 06:16:41

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:44:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-21T23:16:21', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '14ccdc78-c6a1-4eb9-98f3-e5e8f3072338'	System	22 Sep 2020 06:16:41
User entered 'None (0)'	System	22 Sep 2020 06:16:41

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:44:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-21T23:16:23', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '14ccdc78-c6a1-4eb9-98f3-e5e8f3072338'	System	22 Sep 2020 06:16:41
User entered 'None (0)'	System	22 Sep 2020 06:16:41

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:44:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-21T23:16:25', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '14ccdc78-c6a1-4eb9-98f3-e5e8f3072338'		22 Sep 2020 06:16:41
User entered 'None (0)'	System	22 Sep 2020 06:16:41

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:44:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-21T23:16:28', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '14ccdc78-c6a1-4eb9-98f3-e5e8f3072338'	System	22 Sep 2020 06:16:41
User entered 'None (0)'	System	22 Sep 2020 06:16:41

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:44:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-21T23:16:29', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '14ccdc78-c6a1-4eb9-98f3-e5e8f3072338'	System	22 Sep 2020 06:16:41
User entered 'None (0)'	System	22 Sep 2020 06:16:41

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:44:05

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 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-21T23:16:33', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '14ccdc78-c6a1-4eb9-98f3-e5e8f3072338'		22 Sep 2020 06:16:41
User entered 'No (N)'	System	22 Sep 2020 06:16:41

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:44:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-21T23:16:40', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '14ccdc78-c6a1-4eb9-98f3-e5e8f3072338'	System	22 Sep 2020 06:16:41
User entered '21 Sep 2020 23:16'	System	22 Sep 2020 06:16:41

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:44:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:44:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
Data entry locked.	System	16 Sep 2020 19:18:57
User entered 'Day 7'	System	16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:44:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-22T23:17:23', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '6bbe9e6c-a643-4ac3-96dc-888a0714a8e3'	System	23 Sep 2020 06:21:12
User entered 'None (0)'	System	23 Sep 2020 06:21:12

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:44:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-22T23:17:25', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '6bbe9e6c-a643-4ac3-96dc-888a0714a8e3'	System	23 Sep 2020 06:21:12
User entered 'None (0)'	System	23 Sep 2020 06:21:12

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:44:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-22T23:17:27', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '6bbe9e6c-a643-4ac3-96dc-888a0714a8e3'	System	23 Sep 2020 06:21:12
User entered 'None (0)'	System	23 Sep 2020 06:21:12

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:44:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-22T23:17:29', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '6bbe9e6c-a643-4ac3-96dc-888a0714a8e3'	System	23 Sep 2020 06:21:12
User entered 'None (0)'	System	23 Sep 2020 06:21:12

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:44:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-22T23:17:32', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '6bbe9e6c-a643-4ac3-96dc-888a0714a8e3'	System	23 Sep 2020 06:21:12
User entered 'None (0)'	System	23 Sep 2020 06:21:12

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:44:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-22T23:17:35', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '6bbe9e6c-a643-4ac3-96dc-888a0714a8e3'	System	23 Sep 2020 06:21:12
User entered 'None (0)'	System	23 Sep 2020 06:21:12

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:44:05

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 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-22T23:17:37', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '6bbe9e6c-a643-4ac3-96dc-888a0714a8e3'	System	23 Sep 2020 06:21:12
User entered 'No (N)'	System	23 Sep 2020 06:21:12

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:44:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-09-22T23:21:06', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '6bbe9e6c-a643-4ac3-96dc-888a0714a8e3'	System	23 Sep 2020 06:21:12
User entered '22 Sep 2020 23:21'	System	23 Sep 2020 06:21:12

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:44:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '22 Sep 2020 12:00'		16 Sep 2020 19:18:57

US3462244

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:44:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 19:18:57

US3462244

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:37
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	03 Nov 2020 23:41:39

US3462244

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:37
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '23 Sep 2020'	(b) (4) Danuel Hamlin (b) (4)	03 Nov 2020 23:41:39

US3462244

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:37
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danuel Hamlin (b) (4)	03 Nov 2020 23:41:39

US3462244

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:37
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	03 Nov 2020 23:41:39

US3462244

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:37
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	03 Nov 2020 23:41:48

US3462244

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:37
User entered 'I'	System	03 Nov 2020 23:41:48

US3462244

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:37
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	03 Nov 2020 23:42:28

US3462244

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:37
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '30 Sep 2020'	(b) (4) Danuel Hamlin (b) (4)	03 Nov 2020 23:42:28

US3462244

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:37
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danuel Hamlin (b) (4)	03 Nov 2020 23:42:28

US3462244

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:37
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	03 Nov 2020 23:42:28

US3462244

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:37
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	03 Nov 2020 23:46:00

US3462244

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:37
User entered 'I'	System	03 Nov 2020 23:46:00

US3462244

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:37
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	03 Nov 2020 23:46:42

US3462244

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:37
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered '07 Oct 2020'	(b) (4) Danuel Hamlin (b) (4)	03 Nov 2020 23:46:42

US3462244

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:37
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danuel Hamlin (b) (4)	03 Nov 2020 23:46:42

US3462244

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:37
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	03 Nov 2020 23:46:42

US3462244

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:37
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:39:51
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	03 Nov 2020 23:46:51

US3462244

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:37
User entered 'I'	System	03 Nov 2020 23:46:51

US3462244

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:40:12
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	03 Nov 2020 23:47:18

US3462244

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:40:12
User entered '14 Oct 2020'	(b) (4) Danuel Hamlin (b) (4)	03 Nov 2020 23:47:18

US3462244

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:40:12
User entered 'Clinic (Clinic)'	(b) (4) Danuel Hamlin (b) (4)	03 Nov 2020 23:47:18

US3462244

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User entered 'VISIT3'	System	03 Nov 2020 23:47:18

US3462244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:40:12
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	03 Nov 2020 23:47:31

US3462244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:40:12
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	03 Nov 2020 23:47:31

US3462244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:40:12
User entered empty.	Danuel Hamlin (b) (4)	03 Nov 2020 23:47:31

US3462244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User entered empty.	System	03 Nov 2020 23:47:31

US3462244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:40:12
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	03 Nov 2020 23:47:31

US3462244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:40:12
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	03 Nov 2020 23:47:31

US3462244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:40:12
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	03 Nov 2020 23:47:31

US3462244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:40:12
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	03 Nov 2020 23:47:31

US3462244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User entered empty.	System	03 Nov 2020 23:47:31

US3462244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:40:12
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	03 Nov 2020 23:47:31

US3462244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User entered empty.	System	03 Nov 2020 23:47:31

US3462244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:40:12
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	03 Nov 2020 23:47:31

US3462244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User entered empty.	System	03 Nov 2020 23:47:31

US3462244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:40:12
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	03 Nov 2020 23:47:31

US3462244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User entered empty.	System	03 Nov 2020 23:47:31

US3462244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47

US3462244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47

US3462244

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:44:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:40:12
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	03 Nov 2020 23:47:41

US3462244

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:44:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:40:12
User entered empty.	Danuel Hamlin (b) (4)	03 Nov 2020 23:47:41

US3462244

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:44:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:40:12
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	03 Nov 2020 23:48:00

US3462244

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:44:05

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:40:12
User entered '14 Oct 2020'	(b) (4) Danuel Hamlin (b) (4)	03 Nov 2020 23:48:00

US3462244

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:44:05

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:40:12
User entered '11:26'	(b) (4) Danuel Hamlin (b) (4)	03 Nov 2020 23:48:00

US3462244

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:44:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User entered '14 Oct 2020 11:26'	System	03 Nov 2020 23:48:00

US3462244

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:40:12
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	03 Nov 2020 23:48:15

US3462244

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:47
User entered 'I'	System	03 Nov 2020 23:48:15

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
Data entry locked.	System	19 Aug 2020 18:42:58
User entered 'Day 64'	System	19 Aug 2020 18:42:58

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[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 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-10-22T20:03:01', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'fd86c294-d768-4dc3-8f28-d55c66b450f1'	System	23 Oct 2020 03:03:20
User entered 'No (N)'	System	23 Oct 2020 03:03:20

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

Have you been exposed to someone with 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 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-10-22T20:03:12', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'fd86c294-d768-4dc3-8f28-d55c66b450f1'	System	23 Oct 2020 03:03:20
User entered 'No (N)'	System	23 Oct 2020 03:03:20

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-10-22T20:03:16', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'fd86c294-d768-4dc3-8f28-d55c66b450f1'		23 Oct 2020 03:03:20
User entered '22 Oct 2020 20:03:16'	System	23 Oct 2020 03:03:20

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
Data entry locked.	System	19 Aug 2020 18:42:58
User entered '19 Oct 2020 00:01'	System	19 Aug 2020 18:42:58

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
Data entry locked.	System	19 Aug 2020 18:42:58
User entered '23 Oct 2020 23:59'	System	19 Aug 2020 18:42:58

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
Data entry locked.	System	19 Aug 2020 18:42:58
User entered 'Day 71'	System	19 Aug 2020 18:42:58

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[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 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-10-30T16:27:13', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'a1819d5a-2497-4810-8520-8bfd26ccbb9'	System	30 Oct 2020 23:30:21
User entered 'Yes (Y)'	System	30 Oct 2020 23:30:21

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

Have you been exposed to someone with 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 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-10-30T16:27:18', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'a1819d5a-2497-4810-8520-8bfd26ccbb9'	System	30 Oct 2020 23:30:21
User entered 'No (N)'	System	30 Oct 2020 23:30:21

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[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 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-10-30T16:27:47', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'a1819d5a-2497-4810-8520-8bfd26ccbb9'	System	30 Oct 2020 23:30:21
User entered 'Yes (Y)'	System	30 Oct 2020 23:30:21

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-10-30T16:28:23', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'a1819d5a-2497-4810-8520-8bfd26ccbb9'	System	30 Oct 2020 23:30:21
User entered '0'	System	30 Oct 2020 23:30:21

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-10-30T16:28:23', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'a1819d5a-2497-4810-8520-8bfd26ccbb9'	System	30 Oct 2020 23:30:21
User entered '0'	System	30 Oct 2020 23:30:21

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-10-30T16:28:23', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'a1819d5a-2497-4810-8520-8bfd26ccbb9'	System	30 Oct 2020 23:30:21
User entered '1'	System	30 Oct 2020 23:30:21

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-10-30T16:28:23', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'a1819d5a-2497-4810-8520-8bfd26ccbb9'	System	30 Oct 2020 23:30:21
User entered '0'	System	30 Oct 2020 23:30:21

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-10-30T16:28:23', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'a1819d5a-2497-4810-8520-8bfd26ccbb9'	System	30 Oct 2020 23:30:21
User entered '0'	System	30 Oct 2020 23:30:21

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-10-30T16:28:23', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'a1819d5a-2497-4810-8520-8bfd26ccbb9'	System	30 Oct 2020 23:30:21
User entered '0'	System	30 Oct 2020 23:30:21

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-10-30T16:28:23', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'a1819d5a-2497-4810-8520-8bfd26ccbb9'	System	30 Oct 2020 23:30:21
User entered '0'	System	30 Oct 2020 23:30:21

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-10-30T16:28:23', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'a1819d5a-2497-4810-8520-8bfd26ccbb9'	System	30 Oct 2020 23:30:21
User entered '0'	System	30 Oct 2020 23:30:21

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-10-30T16:28:23', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'a1819d5a-2497-4810-8520-8bfd26ccbb9'	System	30 Oct 2020 23:30:21
User entered '1'	System	30 Oct 2020 23:30:21

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-10-30T16:28:23', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'a1819d5a-2497-4810-8520-8bfd26ccbb9'	System	30 Oct 2020 23:30:21
User entered '0'	System	30 Oct 2020 23:30:21

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-10-30T16:28:23', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'a1819d5a-2497-4810-8520-8bfd26ccbb9'	System	30 Oct 2020 23:30:21
User entered '0'	System	30 Oct 2020 23:30:21

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-10-30T16:28:23', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'a1819d5a-2497-4810-8520-8bfd26ccbb9'		30 Oct 2020 23:30:21
User entered '1'	System	30 Oct 2020 23:30:21

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-10-30T16:28:23', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'a1819d5a-2497-4810-8520-8bfd26ccbb9'	System	30 Oct 2020 23:30:21
User entered '0'	System	30 Oct 2020 23:30:21

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-10-30T16:28:23', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'a1819d5a-2497-4810-8520-8bfd26ccbb9'		30 Oct 2020 23:30:21
User entered '0'	System	30 Oct 2020 23:30:21

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-10-30T16:28:23', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'a1819d5a-2497-4810-8520-8bfd26ccbb9'	System	30 Oct 2020 23:30:21
User entered '0'	System	30 Oct 2020 23:30:21

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-10-30T16:28:23', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'a1819d5a-2497-4810-8520-8bfd26ccbb9'	System	30 Oct 2020 23:30:21
User entered '0'	System	30 Oct 2020 23:30:21

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-10-30T16:28:23', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'a1819d5a-2497-4810-8520-8bfd26ccbb9'		30 Oct 2020 23:30:21
User entered '0'	System	30 Oct 2020 23:30:21

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Please 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 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-10-30T16:28:30', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'a1819d5a-2497-4810-8520-8bfd26ccbb9'	System	30 Oct 2020 23:30:21
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	30 Oct 2020 23:30:21

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[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 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-10-30T16:28:57', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'a1819d5a-2497-4810-8520-8bfd26ccbb9'	System	30 Oct 2020 23:30:21
User entered 'No (N)'	System	30 Oct 2020 23:30:21

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-10-30T16:30:12', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'a1819d5a-2497-4810-8520-8bfd26ccbb9'	System	30 Oct 2020 23:30:21
User entered '30 Oct 2020 16:30:12'	System	30 Oct 2020 23:30:21

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
Data entry locked.	System	19 Aug 2020 18:42:58
User entered '26 Oct 2020 00:01'	System	19 Aug 2020 18:42:58

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
Data entry locked.	System	19 Aug 2020 18:42:58
User entered '30 Oct 2020 23:59'	System	19 Aug 2020 18:42:58

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
Data entry locked.	System	19 Aug 2020 18:42:58
User entered 'Day 78'	System	19 Aug 2020 18:42:58

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[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 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-11-06T18:17:15', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '58d3db02-7356-4951-948f-2f44ee46610d'	System	07 Nov 2020 02:18:16
User entered 'Yes (Y)'	System	07 Nov 2020 02:18:16

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

Have you been exposed to someone with 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 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-11-06T18:17:23', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '58d3db02-7356-4951-948f-2f44ee46610d'	System	07 Nov 2020 02:18:16
User entered 'No (N)'	System	07 Nov 2020 02:18:16

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[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 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-11-06T18:17:27', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '58d3db02-7356-4951-948f-2f44ee46610d'	System	07 Nov 2020 02:18:16
User entered 'No (N)'	System	07 Nov 2020 02:18:16

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[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 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-11-06T18:17:39', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '58d3db02-7356-4951-948f-2f44ee46610d'	System	07 Nov 2020 02:18:16
User entered 'Yes (Y)'	System	07 Nov 2020 02:18:16

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Please 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 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-11-06T18:17:45', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '58d3db02-7356-4951-948f-2f44ee46610d'	System	07 Nov 2020 02:18:16
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	07 Nov 2020 02:18:16

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-11-06T18:18:00', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '58d3db02-7356-4951-948f-2f44ee46610d'	System	07 Nov 2020 02:18:16
User entered '06 Nov 2020 18:18:00'	System	07 Nov 2020 02:18:16

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
Data entry locked.	System	19 Aug 2020 18:42:58
User entered '02 Nov 2020 00:01'	System	19 Aug 2020 18:42:58

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:26:42
Data entry locked.	System	19 Aug 2020 18:42:58
User entered '06 Nov 2020 23:59'	System	19 Aug 2020 18:42:58

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:46:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:07:46
Data entry locked.	System	19 Aug 2020 18:42:58
User entered 'Day 92'	System	19 Aug 2020 18:42:58

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[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 Apr 2021 12:46:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:07:46

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Have you been exposed to someone with 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 Apr 2021 12:46:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:07:46

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Please 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 Apr 2021 12:46:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:07:46

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[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 Apr 2021 12:46:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:07:46

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:46:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:07:46

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:46:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:07:46

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:46:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:07:46

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:46:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:07:46

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:46:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:07:46

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:46:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:07:46

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:46:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:07:46

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:46:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:07:46

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:46:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:07:46

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:46:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:07:46

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:46:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:07:46

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:46:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:07:46

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:46:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:07:46

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:46:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:07:46

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:46:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:07:46

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:46:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:07:46

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:46:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:07:46

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Please 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 Apr 2021 12:46:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:07:46

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[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 Apr 2021 12:46:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:07:46

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Please 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 Apr 2021 12:46:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:07:46

US3462244

Folder: Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:46:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:07:46

US3462244

Folder: Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:46:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:07:46
Data entry locked.	System	19 Aug 2020 18:42:58
User entered '16 Nov 2020 00:01'	System	19 Aug 2020 18:42:58

US3462244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:46:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:07:46
Data entry locked.	System	19 Aug 2020 18:42:58
User entered '20 Nov 2020 23:59'	System	19 Aug 2020 18:42:58

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[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 (e60522ca3c8628fa)', Time: '2020-11-20T17:36:21', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '58f889ea-a879-4585-ad4d-23ae48c4d977'	System	21 Nov 2020 01:37:36
User entered 'No (N)'	System	21 Nov 2020 01:37:36

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

Have you been exposed to someone with 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 (e60522ca3c8628fa)', Time: '2020-11-20T17:36:26', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '58f889ea-a879-4585-ad4d-23ae48c4d977'	System	21 Nov 2020 01:37:36
User entered 'No (N)'	System	21 Nov 2020 01:37:36

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-11-20T17:37:32', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '58f889ea-a879-4585-ad4d-23ae48c4d977'	System	21 Nov 2020 01:37:36
User entered '20 Nov 2020 17:37:32'	System	21 Nov 2020 01:37:36

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[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 (e60522ca3c8628fa)', Time: '2020-11-27T17:30:37', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'e9f99880-7eec-465e-a089-aa2500ae6de4'	System	28 Nov 2020 01:30:52
User entered 'No (N)'	System	28 Nov 2020 01:30:52

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Have you been exposed to someone with 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 (e60522ca3c8628fa)', Time: '2020-11-27T17:30:43', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'e9f99880-7eec-465e-a089-aa2500ae6de4'	System	28 Nov 2020 01:30:52
User entered 'No (N)'	System	28 Nov 2020 01:30:52

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-11-27T17:30:46', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'e9f99880-7eec-465e-a089-aa2500ae6de4'	System	28 Nov 2020 01:30:52
User entered '27 Nov 2020 17:30:46'	System	28 Nov 2020 01:30:52

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[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 (e60522ca3c8628fa)', Time: '2020-12-04T13:41:27', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '7b3c51f8-813c-418a-bd03-c62131a1812c'	System	04 Dec 2020 21:44:14
User entered 'Yes (Y)'	System	04 Dec 2020 21:44:14

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

Have you been exposed to someone with 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 (e60522ca3c8628fa)', Time: '2020-12-04T13:41:33', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '7b3c51f8-813c-418a-bd03-c62131a1812c'	System	04 Dec 2020 21:44:14
User entered 'No (N)'	System	04 Dec 2020 21:44:14

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[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 (e60522ca3c8628fa)', Time: '2020-12-04T13:42:30', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '7b3c51f8-813c-418a-bd03-c62131a1812c'	System	04 Dec 2020 21:44:14
User entered 'Yes (Y)'	System	04 Dec 2020 21:44:14

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-12-04T13:42:44', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '7b3c51f8-813c-418a-bd03-c62131a1812c'	System	04 Dec 2020 21:44:14
User entered '0'	System	04 Dec 2020 21:44:14

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-12-04T13:42:44', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '7b3c51f8-813c-418a-bd03-c62131a1812c'	System	04 Dec 2020 21:44:14
User entered '0'	System	04 Dec 2020 21:44:14

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-12-04T13:42:44', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '7b3c51f8-813c-418a-bd03-c62131a1812c'	System	04 Dec 2020 21:44:14
User entered '0'	System	04 Dec 2020 21:44:14

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-12-04T13:42:44', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '7b3c51f8-813c-418a-bd03-c62131a1812c'	System	04 Dec 2020 21:44:14
User entered '0'	System	04 Dec 2020 21:44:14

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-12-04T13:42:44', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '7b3c51f8-813c-418a-bd03-c62131a1812c'	System	04 Dec 2020 21:44:14
User entered '0'	System	04 Dec 2020 21:44:14

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-12-04T13:42:44', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '7b3c51f8-813c-418a-bd03-c62131a1812c'	System	04 Dec 2020 21:44:14
User entered '0'	System	04 Dec 2020 21:44:14

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-12-04T13:42:44', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '7b3c51f8-813c-418a-bd03-c62131a1812c'	System	04 Dec 2020 21:44:14
User entered '0'	System	04 Dec 2020 21:44:14

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-12-04T13:42:44', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '7b3c51f8-813c-418a-bd03-c62131a1812c'	System	04 Dec 2020 21:44:14
User entered '0'	System	04 Dec 2020 21:44:14

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-12-04T13:42:44', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '7b3c51f8-813c-418a-bd03-c62131a1812c'	System	04 Dec 2020 21:44:14
User entered '0'	System	04 Dec 2020 21:44:14

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-12-04T13:42:44', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '7b3c51f8-813c-418a-bd03-c62131a1812c'	System	04 Dec 2020 21:44:14
User entered '0'	System	04 Dec 2020 21:44:14

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-12-04T13:42:44', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '7b3c51f8-813c-418a-bd03-c62131a1812c'	System	04 Dec 2020 21:44:14
User entered '0'	System	04 Dec 2020 21:44:14

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-12-04T13:42:44', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '7b3c51f8-813c-418a-bd03-c62131a1812c'	System	04 Dec 2020 21:44:14
User entered '0'	System	04 Dec 2020 21:44:14

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-12-04T13:42:44', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '7b3c51f8-813c-418a-bd03-c62131a1812c'	System	04 Dec 2020 21:44:14
User entered '0'	System	04 Dec 2020 21:44:14

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-12-04T13:42:44', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '7b3c51f8-813c-418a-bd03-c62131a1812c' User entered '0'	System	04 Dec 2020 21:44:14

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-12-04T13:42:44', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '7b3c51f8-813c-418a-bd03-c62131a1812c'	System	04 Dec 2020 21:44:14
User entered '0'	System	04 Dec 2020 21:44:14

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-12-04T13:42:44', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '7b3c51f8-813c-418a-bd03-c62131a1812c'	System	04 Dec 2020 21:44:14
User entered '0'	System	04 Dec 2020 21:44:14

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-12-04T13:42:44', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '7b3c51f8-813c-418a-bd03-c62131a1812c'	System	04 Dec 2020 21:44:14
User entered '1'	System	04 Dec 2020 21:44:14

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Please 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 (e60522ca3c8628fa)', Time: '2020-12-04T13:43:06', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '7b3c51f8-813c-418a-bd03-c62131a1812c'	System	04 Dec 2020 21:44:14
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	04 Dec 2020 21:44:14

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[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 (e60522ca3c8628fa)', Time: '2020-12-04T13:43:17', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '7b3c51f8-813c-418a-bd03-c62131a1812c'	System	04 Dec 2020 21:44:14
User entered 'No (N)'	System	04 Dec 2020 21:44:14

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-12-04T13:43:58', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '7b3c51f8-813c-418a-bd03-c62131a1812c' User entered '04 Dec 2020 13:43:58'	System	04 Dec 2020 21:44:14
	System	04 Dec 2020 21:44:14

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[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 (e60522ca3c8628fa)', Time: '2020-12-11T20:35:02', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '79726250-61e3-4f9c-8413-2846a4b10713'	System	12 Dec 2020 04:35:14
User entered 'No (N)'	System	12 Dec 2020 04:35:14

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

Have you been exposed to someone with 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 (e60522ca3c8628fa)', Time: '2020-12-11T20:35:05', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '79726250-61e3-4f9c-8413-2846a4b10713'	System	12 Dec 2020 04:35:14
User entered 'No (N)'	System	12 Dec 2020 04:35:14

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2020-12-11T20:35:09', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '79726250-61e3-4f9c-8413-2846a4b10713'	System	12 Dec 2020 04:35:14
User entered '11 Dec 2020 20:35:09'	System	12 Dec 2020 04:35:14

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[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 (e60522ca3c8628fa)', Time: '2021-01-01T12:44:41', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '47beef3a-efba-4754-ac1b-744df2fab8c8'	System	01 Jan 2021 20:44:52
User entered 'No (N)'	System	01 Jan 2021 20:44:52

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

Have you been exposed to someone with 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 (e60522ca3c8628fa)', Time: '2021-01-01T12:44:45', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '47beef3a-efba-4754-ac1b-744df2fab8c8'	System	01 Jan 2021 20:44:52
User entered 'No (N)'	System	01 Jan 2021 20:44:52

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2021-01-01T12:44:50', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '47beef3a-efba-4754-ac1b-744df2fab8c8'	System	01 Jan 2021 20:44:52
User entered '01 Jan 2021 12:44:50'	System	01 Jan 2021 20:44:52

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[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 (e60522ca3c8628fa)', Time: '2021-01-08T12:21:42', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '7f1545fb-c8ee-4741-82cc-bb856771d02f'	System	08 Jan 2021 20:21:53
User entered 'No (N)'	System	08 Jan 2021 20:21:53

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

Have you been exposed to someone with 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 (e60522ca3c8628fa)', Time: '2021-01-08T12:21:46', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '7f1545fb-c8ee-4741-82cc-bb856771d02f'	System	08 Jan 2021 20:21:53
User entered 'No (N)'	System	08 Jan 2021 20:21:53

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2021-01-08T12:21:49', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '7f1545fb-c8ee-4741-82cc-bb856771d02f' User entered '08 Jan 2021 12:21:49'	System	08 Jan 2021 20:21:53

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[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 (e60522ca3c8628fa)', Time: '2021-01-23T10:16:26', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'cc9f0c7c-116a-498a-81e2-1f2d38ece645'	System	23 Jan 2021 18:16:57
User entered 'No (N)'	System	23 Jan 2021 18:16:57

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

Have you been exposed to someone with 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 (e60522ca3c8628fa)', Time: '2021-01-23T10:16:37', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'cc9f0c7c-116a-498a-81e2-1f2d38ece645'	System	23 Jan 2021 18:16:57
User entered 'Yes (Y)'	System	23 Jan 2021 18:16:57

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

Please 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 (e60522ca3c8628fa)', Time: '2021-01-23T10:16:42', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'cc9f0c7c-116a-498a-81e2-1f2d38ece645'	System	23 Jan 2021 18:16:57
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	23 Jan 2021 18:16:57

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2021-01-23T10:16:48', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'cc9f0c7c-116a-498a-81e2-1f2d38ece645'	System	23 Jan 2021 18:16:57
User entered '23 Jan 2021 10:16:48'	System	23 Jan 2021 18:16:57

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[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 (e60522ca3c8628fa)', Time: '2021-01-29T16:41:22', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'ed7e34c5-cc8f-4d4c-b81f-5306b64c99fa'	System	30 Jan 2021 00:41:46
User entered 'No (N)'	System	30 Jan 2021 00:41:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

Have you been exposed to someone with 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 (e60522ca3c8628fa)', Time: '2021-01-29T16:41:29', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'ed7e34c5-cc8f-4d4c-b81f-5306b64c99fa'	System	30 Jan 2021 00:41:46
User entered 'Yes (Y)'	System	30 Jan 2021 00:41:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Please 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 (e60522ca3c8628fa)', Time: '2021-01-29T16:41:32', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'ed7e34c5-cc8f-4d4c-b81f-5306b64c99fa'	System	30 Jan 2021 00:41:46
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	30 Jan 2021 00:41:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2021-01-29T16:41:36', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'ed7e34c5-cc8f-4d4c-b81f-5306b64c99fa'	System	30 Jan 2021 00:41:46
User entered '29 Jan 2021 16:41:36'	System	30 Jan 2021 00:41:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[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 (e60522ca3c8628fa)', Time: '2021-02-05T15:11:37', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '75211cfe-e824-4d96-b3bf-7d8c66909538'	System	05 Feb 2021 23:12:39
User entered 'No (N)'	System	05 Feb 2021 23:12:39

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

Have you been exposed to someone with 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 (e60522ca3c8628fa)', Time: '2021-02-05T15:11:44', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '75211cfe-e824-4d96-b3bf-7d8c66909538'	System	05 Feb 2021 23:12:39
User entered 'No (N)'	System	05 Feb 2021 23:12:39

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2021-02-05T15:11:53', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '75211cfe-e824-4d96-b3bf-7d8c66909538'	System	05 Feb 2021 23:12:39
User entered '05 Feb 2021 15:11:53'	System	05 Feb 2021 23:12:39

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[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 (e60522ca3c8628fa)', Time: '2021-02-19T23:34:25', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '5e1f4e69-0dc5-4cf3-b4ea-d04ab96adde4'	System	20 Feb 2021 07:34:40
User entered 'No (N)'	System	20 Feb 2021 07:34:40

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

Have you been exposed to someone with 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 (e60522ca3c8628fa)', Time: '2021-02-19T23:34:30', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '5e1f4e69-0dc5-4cf3-b4ea-d04ab96adde4'	System	20 Feb 2021 07:34:40
User entered 'No (N)'	System	20 Feb 2021 07:34:40

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2021-02-19T23:34:35', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '5e1f4e69-0dc5-4cf3-b4ea-d04ab96adde4' User entered '19 Feb 2021 23:34:35'	System	20 Feb 2021 07:34:40

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[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 (e60522ca3c8628fa)', Time: '2021-03-02T23:12:57', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'a7b99552-da24-4f14-a480-517bc789ec25'	System	03 Mar 2021 07:13:17
User entered 'No (N)'	System	03 Mar 2021 07:13:17

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Have you been exposed to someone with 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 (e60522ca3c8628fa)', Time: '2021-03-02T23:13:02', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'a7b99552-da24-4f14-a480-517bc789ec25'	System	03 Mar 2021 07:13:17
User entered 'No (N)'	System	03 Mar 2021 07:13:17

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2021-03-02T23:13:11', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'a7b99552-da24-4f14-a480-517bc789ec25'	System	03 Mar 2021 07:13:17
User entered '02 Mar 2021 23:13:11'	System	03 Mar 2021 07:13:17

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[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 (e60522ca3c8628fa)', Time: '2021-03-09T18:48:59', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'bb13810a-e49f-4d76-9ba0-fe53c5ad794c'	System	10 Mar 2021 02:49:48
User entered 'No (N)'	System	10 Mar 2021 02:49:48

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

Have you been exposed to someone with 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 (e60522ca3c8628fa)', Time: '2021-03-09T18:49:02', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'bb13810a-e49f-4d76-9ba0-fe53c5ad794c'	System	10 Mar 2021 02:49:48
User entered 'No (N)'	System	10 Mar 2021 02:49:48

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2021-03-09T18:49:13', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'bb13810a-e49f-4d76-9ba0-fe53c5ad794c'	System	10 Mar 2021 02:49:48
User entered '09 Mar 2021 18:49:13'	System	10 Mar 2021 02:49:48

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[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 (e60522ca3c8628fa)', Time: '2021-03-16T20:30:41', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'de0ee6f6-40a0-42e6-8512-251fd345260b'	System	17 Mar 2021 03:30:51
User entered 'No (N)'	System	17 Mar 2021 03:30:51

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

Have you been exposed to someone with 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 (e60522ca3c8628fa)', Time: '2021-03-16T20:30:43', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'de0ee6f6-40a0-42e6-8512-251fd345260b'	System	17 Mar 2021 03:30:51
User entered 'No (N)'	System	17 Mar 2021 03:30:51

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2021-03-16T20:30:47', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'de0ee6f6-40a0-42e6-8512-251fd345260b' User entered '16 Mar 2021 20:30:47'	System	17 Mar 2021 03:30:51

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[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 (e60522ca3c8628fa)', Time: '2021-03-23T18:37:05', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '25f53a28-982c-4572-8928-5c27a4adf82f'	System	24 Mar 2021 01:37:17
User entered 'No (N)'	System	24 Mar 2021 01:37:17

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

Have you been exposed to someone with 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 (e60522ca3c8628fa)', Time: '2021-03-23T18:37:10', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '25f53a28-982c-4572-8928-5c27a4adf82f'	System	24 Mar 2021 01:37:17
User entered 'No (N)'	System	24 Mar 2021 01:37:17

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2021-03-23T18:37:13', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '25f53a28-982c-4572-8928-5c27a4adf82f' User entered '23 Mar 2021 18:37:13'	System	24 Mar 2021 01:37:17

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[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 (e60522ca3c8628fa)', Time: '2021-03-30T20:45:19', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'd62173d4-2122-4025-8750-52e259e03414'	System	31 Mar 2021 03:45:28
User entered 'No (N)'	System	31 Mar 2021 03:45:28

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

Have you been exposed to someone with 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 (e60522ca3c8628fa)', Time: '2021-03-30T20:45:21', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'd62173d4-2122-4025-8750-52e259e03414'	System	31 Mar 2021 03:45:28
User entered 'No (N)'	System	31 Mar 2021 03:45:28

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2021-03-30T20:45:25', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'd62173d4-2122-4025-8750-52e259e03414'	System	31 Mar 2021 03:45:28
User entered '30 Mar 2021 20:45:25'	System	31 Mar 2021 03:45:28

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[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 (e60522ca3c8628fa)', Time: '2021-04-06T21:19:44', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'ce53357b-9703-4926-a9b6-f704b693bf78'	System	07 Apr 2021 04:19:59
User entered 'No (N)'	System	07 Apr 2021 04:19:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Have you been exposed to someone with 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 (e60522ca3c8628fa)', Time: '2021-04-06T21:19:50', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'ce53357b-9703-4926-a9b6-f704b693bf78'	System	07 Apr 2021 04:19:59
User entered 'No (N)'	System	07 Apr 2021 04:19:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2021-04-06T21:19:54', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'ce53357b-9703-4926-a9b6-f704b693bf78'	System	07 Apr 2021 04:19:59
User entered '06 Apr 2021 21:19:54'	System	07 Apr 2021 04:19:59

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[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 (e60522ca3c8628fa)', Time: '2021-04-13T20:41:33', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '88b6631e-5dc8-4bc8-acb0-a5005f1765b5'	System	14 Apr 2021 03:42:10
User entered 'Yes (Y)'	System	14 Apr 2021 03:42:10

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

Have you been exposed to someone with 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 (e60522ca3c8628fa)', Time: '2021-04-13T20:41:36', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '88b6631e-5dcb-4bc8-acb0-a5005f1765b5'	System	14 Apr 2021 03:42:10
User entered 'No (N)'	System	14 Apr 2021 03:42:10

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[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 (e60522ca3c8628fa)', Time: '2021-04-13T20:41:41', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '88b6631e-5dcb-4bc8-acb0-a5005f1765b5'	System	14 Apr 2021 03:42:10
User entered 'No (N)'	System	14 Apr 2021 03:42:10

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[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 (e60522ca3c8628fa)', Time: '2021-04-13T20:41:52', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '88b6631e-5dcb-4bc8-acb0-a5005f1765b5'	System	14 Apr 2021 03:42:10
User entered 'Yes (Y)'	System	14 Apr 2021 03:42:10

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

Please 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 (e60522ca3c8628fa)', Time: '2021-04-13T20:41:55', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '88b6631e-5dcb-4bc8-acb0-a5005f1765b5'	System	14 Apr 2021 03:42:10
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	14 Apr 2021 03:42:10

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2021-04-13T20:41:59', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: '88b6631e-5dc8-4bc8-acb0-a5005f1765b5'	System	14 Apr 2021 03:42:10
User entered '13 Apr 2021 20:41:59'	System	14 Apr 2021 03:42:10

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[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 (e60522ca3c8628fa)', Time: '2021-04-20T16:00:58', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'b0274221-03fc-46bf-80b1-677a5a2236d2'	System	20 Apr 2021 23:02:22
User entered 'No (N)'	System	20 Apr 2021 23:02:22

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

Have you been exposed to someone with 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 (e60522ca3c8628fa)', Time: '2021-04-20T16:01:01', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'b0274221-03fc-46bf-80b1-677a5a2236d2'	System	20 Apr 2021 23:02:22
User entered 'No (N)'	System	20 Apr 2021 23:02:22

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2021-04-20T16:01:05', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'b0274221-03fc-46bf-80b1-677a5a2236d2'	System	20 Apr 2021 23:02:22
User entered '20 Apr 2021 16:01:05'	System	20 Apr 2021 23:02:22

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[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 (e60522ca3c8628fa)', Time: '2021-04-27T15:56:40', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'e15f67db-f439-405e-b839-d015b10c3f62'	System	28 Apr 2021 23:49:38
User entered 'No (N)'	System	28 Apr 2021 23:49:38

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

Have you been exposed to someone with 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 (e60522ca3c8628fa)', Time: '2021-04-27T15:56:44', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'e15f67db-f439-405e-b839-d015b10c3f62'	System	28 Apr 2021 23:49:38
User entered 'No (N)'	System	28 Apr 2021 23:49:38

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2021-04-27T15:56:50', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'e15f67db-f439-405e-b839-d015b10c3f62'	System	28 Apr 2021 23:49:38
User entered '27 Apr 2021 15:56:50'	System	28 Apr 2021 23:49:38

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '21 Oct 2022 00:01'	System	19 Nov 2020 23:07:46

US3462244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:46
Amendment Manager: User entered '25 Oct 2022 23:59'	System	19 Nov 2020 23:07:46

US3462244

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:44:05

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 12:46:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2021-02-27T03:43:22', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'f27ca466-c8ce-42ab-8210-34fa2d04a74a'	System	27 Feb 2021 11:43:35
User entered 'No (N)'	System	27 Feb 2021 11:43:35

US3462244

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:44:05

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:46:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e60522ca3c8628fa)', Time: '2021-02-27T03:43:31', User OID: 'PatientReportedOutcome (US3462244)', ODM File OID: 'f27ca466-c8ce-42ab-8210-34fa2d04a74a'	System	27 Feb 2021 11:43:35
User entered '27 Feb 2021 03:43:31'	System	27 Feb 2021 11:43:35

US3462244

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:37
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:20:40
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Nov 2020 23:02:13
User entered 'Yes (Y)' reason for change: Data Entry Error	System	17 Nov 2020 23:02:13
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 23:02:13
User entered empty; reason for change Data Entry Error	System	04 Nov 2020 15:15:07
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	04 Nov 2020 15:15:07
	Danuel Hamlin (b) (4)	04 Nov 2020 15:12:37

US3462244

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:05

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:37
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:20:40
User entered '12 Nov 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:02:13
User closed query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	04 Nov 2020 15:15:07
Query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	04 Nov 2020 15:15:07
User entered empty; reason for change Data Entry Error	Danuel Hamlin (b) (4)	04 Nov 2020 15:15:07
User opened query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	04 Nov 2020 15:12:37
User entered '04 Nov 2020'	Danuel Hamlin (b) (4)	04 Nov 2020 15:12:37

US3462244

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:37
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:20:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 15:12:37

US3462244

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:37
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:20:40
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 15:12:37

US3462244

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:37
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:20:40
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 15:12:45

US3462244

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:44:37
User entered 'I'	System	04 Nov 2020 15:12:45

US3462244

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:35
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Jan 2021 21:09:26
User entered 'Yes (Y)' reason for change: Data Entry Error	System	28 Jan 2021 21:09:26
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	28 Jan 2021 21:09:22
User entered empty.	(b) (4), (b) (6)	28 Jan 2021 21:09:22

US3462244

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:05

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:35
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '16 Dec 2020'	(b) (4), (b) (6)	28 Jan 2021 21:09:22

US3462244

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:35
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 21:09:22

US3462244

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:35
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	28 Jan 2021 21:09:22

US3462244

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:35
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Jan 2021 21:09:30

US3462244

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:35
User entered 'I'	System	28 Jan 2021 21:09:30

US3462244

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:35
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:13:50
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 22Jan2021 is reported under OL-1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 12:20:34
User closed query 'Per GCL Lab Reconciliation: Swab: Per GCL, there is a Swab sample collected on 22JAN2021 for the Participant Decision Visit / OL-D1, however, there is no data recorded in the Patient Decision Visit / OL-D1 folder. Please clarify and update as appropriate. ' (Site from DM).		24 Feb 2021 12:20:32
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 22Jan2021 is reported under OL-1 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 missing Data' (Site from DM).		22 Feb 2021 17:50:34
Query 'Per GCL Lab Reconciliation: Swab: Per GCL there is a Swab sample collected on 22JAN2021 for the Participant Decision Visit / OL-D1, however, there is no data recorded in the Patient Decision Visit / OL-D1 folder. Please clarify and update as appropriate. ' answered with 'updated Missing Data' (Site from DM).		22 Feb 2021 17:49:19
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 22Jan2021 is reported under OL-1 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).		09 Feb 2021 13:28:16

US3462244

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Swab: Per GCL, there is a Swab sample collected on 22JAN2021 for the Participant Decision Visit / OL-D1, however, there is no data recorded in the Patient Decision Visit / OL-D1 folder. Please clarify and update as appropriate. ' (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Feb 2021 23:27:21
		28 Jan 2021 21:09:43

US3462244

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:05

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:35
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:13:50
User closed query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	02 Feb 2021 11:18:05
Query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered with 'Confirmed. Patient was unreachable for scheduled phone call, but called back on 21Jan2021.' (Site from System).		28 Jan 2021 21:10:36
User opened query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	28 Jan 2021 21:09:43
User entered '21 Jan 2021'	(b) (4), (b) (6)	28 Jan 2021 21:09:43

US3462244

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:35
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:13:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 21:09:43

US3462244

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:35
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:13:50
User entered empty.	(b) (4), (b) (6)	28 Jan 2021 21:09:43

US3462244

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:35
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Jan 2021 21:10:42

US3462244

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:35
User entered 'I'	System	28 Jan 2021 21:10:42

US3462244

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:35
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:20:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Feb 2021 00:57:14

US3462244

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:05

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:35
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:20:40
User entered '12 Feb 2021'	(b) (4), (b) (6)	16 Feb 2021 00:57:14

US3462244

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:35
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:20:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	16 Feb 2021 00:57:14

US3462244

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:35
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:20:40
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 00:57:14

US3462244

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:35
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Feb 2021 00:57:18

US3462244

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:35
User entered '1'	System	16 Feb 2021 00:57:18

US3462244

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:35
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:13:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Mar 2021 18:51:11

US3462244

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:35
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:13:50
User entered '17 Mar 2021'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:51:11

US3462244

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:35
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:13:50
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:51:11

US3462244

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:35
User entered 'VISIT4'	System	17 Mar 2021 18:51:11

US3462244

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:35
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 22:21:18

US3462244

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:35
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:57
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 22:21:18

US3462244

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:35
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:57
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 22:21:18

US3462244

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:35
User entered empty.	System	29 Mar 2021 22:21:18

US3462244

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:35
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:57
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 22:21:18

US3462244

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:35
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:57
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 22:21:18

US3462244

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:35
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:57
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 22:21:18

US3462244

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:35
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:57
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 22:21:18

US3462244

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:35
User entered empty.	System	29 Mar 2021 22:21:18

US3462244

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:35
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:57
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 22:21:18

US3462244

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:35
User entered empty.	System	29 Mar 2021 22:21:18

US3462244

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:35
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:57
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 22:21:18

US3462244

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:35
User entered empty.	System	29 Mar 2021 22:21:18

US3462244

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:35
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:57
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 22:21:18

US3462244

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:35
User entered empty.	System	29 Mar 2021 22:21:18

US3462244

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:35

US3462244

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:35

US3462244

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:44:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:35
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:13:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:51:18

US3462244

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:44:05

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:35
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:13:50
User entered empty.	(b) (4), (b) (6)	17 Mar 2021 18:51:18

US3462244

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:44:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:35
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:13:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Mar 2021 18:51:32

US3462244

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:44:05

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:35
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:13:50
User entered '17 Mar 2021'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:51:32

US3462244

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:44:05

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:35
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:13:50
User entered '11:32'	(b) (4), (b) (6)	17 Mar 2021 18:51:32

US3462244

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:44:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:35
User entered '17 Mar 2021 11:32'	System	17 Mar 2021 18:51:32

US3462244

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:35
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:13:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Mar 2021 18:51:38

US3462244

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:35
User entered 'I'	System	17 Mar 2021 18:51:38

US3462244

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:25:28

US3462244

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
User entered '15 Apr 2021'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:25:28

US3462244

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:25:28

US3462244

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 21:25:28

US3462244

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:25:33

US3462244

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:05

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Apr 2021 21:25:33

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:44:05

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:58
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 07-DEC-2020 is reported under Illness Visit Day 1 in PPD portal; however, corresponding swab sample is missing in EDC for 07-DEC-2020. Kindly review if the swab sample was collected, if yes, consider updating EDC by initiating Covid -19 Assessment eCRF for the corresponding date, else clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Jan 2021 07:47:46
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 07-DEC-2020 is reported under Illness Visit Day 1 in PPD portal; however, corresponding swab sample is missing in EDC for 07-DEC-2020. Kindly review if the swab sample was collected, if yes, consider updating EDC by initiating Covid -19 Assessment eCRF for the corresponding date, else clarify. ' answered with 'Corrected, second Covid-19 assessment added to EDC' (Site from DM).		14 Jan 2021 19:09:25
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 07-DEC-2020 is reported under Illness Visit Day 1 in PPD portal; however, corresponding swab sample is missing in EDC for 07-DEC-2020. Kindly review if the swab sample was collected, if yes, consider updating EDC by initiating Covid -19 Assessment eCRF for the corresponding date, else clarify. ' (Site from DM).		16 Dec 2020 05:22:10
User entered '01 Nov 2020'	Danuel Hamlin (b) (4)	10 Nov 2020 13:42:36

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:44:05

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:58
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered with 'Time is unknown ' (Site from System).	(b) (4), (b) (6)	15 Dec 2020 10:48:48
Query 'Data is required. Please complete.' answered with 'Time is unknown ' (Site from System).	Danuel Hamlin (b) (4)	10 Nov 2020 13:42:49
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 13:42:36
User entered empty.	Danuel Hamlin (b) (4)	10 Nov 2020 13:42:36

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:44:05

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:58
User entered empty.	System	10 Nov 2020 13:42:36

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:44:05

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:58
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Safety Call (Safety Call)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:42:36

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:44:05

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:58
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:42:36

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Day 1 (Day 1)'	(b) (4) Danuel Hamlin (b) (4)	10 Nov 2020 13:44:27

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '01 Nov 2020'	(b) (4) Danuel Hamlin (b) (4)	10 Nov 2020 13:44:27

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '0'	Danuel Hamlin (b) (4)	10 Nov 2020 13:44:27

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered missing code ND - Not Done.	Danuel Hamlin (b) (4)	10 Nov 2020 13:44:27

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User entered '%'	System	10 Nov 2020 13:44:27

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered missing code ND - Not Done.	Danuel Hamlin (b) (4)	10 Nov 2020 13:44:27

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:44:27

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Mild (Mild)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:44:27

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:44:27

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:44:27

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Moderate (Moderate)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:44:27

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	(b) (4) Danuel Hamlin (b) (4)	10 Nov 2020 13:44:27

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:44:27

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Mild (Mild)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:44:27

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:44:27

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	(b) (4) Danuel Hamlin (b) (4)	10 Nov 2020 13:44:27

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:44:27

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Mild (Mild)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:44:27

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:44:27

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	(b) (4) Danuel Hamlin (b) (4)	10 Nov 2020 13:44:27

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:44:27

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Mild (Mild)'	(b) (4) Danuel Hamlin (b) (4)	10 Nov 2020 13:44:27

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Day 2 (Day 2)'	(b) (4) Danuel Hamlin (b) (4)	10 Nov 2020 13:46:05

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '02 Nov 2020'	Danuel Hamlin (b) (4)	10 Nov 2020 13:46:05

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '0'	Danuel Hamlin (b) (4)	10 Nov 2020 13:46:05

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '98'	Danuel Hamlin (b) (4)	10 Nov 2020 13:46:05

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User entered '%'	System	10 Nov 2020 13:46:05

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '36.8' C	Danuel Hamlin (b) (4)	10 Nov 2020 13:46:05

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:46:05

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Mild (Mild)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:46:05

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:46:05

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:46:05

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Moderate (Moderate)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:46:05

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:05

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:46:05

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:46:05

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Mild (Mild)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:46:05

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:46:05

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:46:05

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:46:05

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Mild (Mild)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:46:05

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:46:05

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:46:05

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:46:05

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Mild (Mild)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:46:05

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Day 3 (Day 3)'	(b) (4) Danuel Hamlin (b) (4)	10 Nov 2020 13:47:32

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '03 Nov 2020'	(b) (4) Danuel Hamlin (b) (4)	10 Nov 2020 13:47:32

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '0'	Danuel Hamlin (b) (4)	10 Nov 2020 13:47:32

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '99'	Danuel Hamlin (b) (4)	10 Nov 2020 13:47:32

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User entered '%'	System	10 Nov 2020 13:47:32

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '98.3' F	Danuel Hamlin (b) (4)	10 Nov 2020 13:47:32

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:47:32

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Mild (Mild)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:47:32

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:47:32

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:47:32

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:47:32

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:05

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:47:32

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:47:32

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:47:32

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:47:32

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:47:32

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:47:32

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Mild (Mild)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:47:32

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:47:32

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:47:32

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:47:32

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:47:32

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User closed query 'Per CDM: Per sponsor review, please verify 'Symptom Days'. Since site has already recorded 'Day 3' as '03Nov2020', please consider updating this form to 'Day 4' for '04Nov2020'. Then update the rest of 'Symptom Days' to follow in sequence with this update, or please clarify.' (Site from DM).		30 Mar 2021 19:37:24
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:57
Signature has been broken.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:09:57
User entered 'Day 4 (Day 4)' reason for change: Data Entry Error		29 Mar 2021 19:09:57
Query 'Per CDM: Per sponsor review, please verify 'Symptom Days'. Since site has already recorded 'Day 3' as '03Nov2020', please consider updating this form to 'Day 4' for '04Nov2020'. Then update the rest of 'Symptom Days' to follow in sequence with this update, or please clarify.' answered with 'Corrected' (Site from DM).		29 Mar 2021 19:08:25
User opened query 'Per CDM: Per sponsor review, please verify 'Symptom Days'. Since site has already recorded 'Day 3' as '03Nov2020', please consider updating this form to 'Day 4' for '04Nov2020'. Then update the rest of 'Symptom Days' to follow in sequence with this update, or please clarify.' (Site from DM).		14 Mar 2021 21:51:48
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Day 3 (Day 3)'	(b) (4) Danael Hamlin (b) (4)	10 Nov 2020 13:48:27

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '04 Nov 2020'	Danuel Hamlin (b) (4)	10 Nov 2020 13:48:27

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '0'	Danuel Hamlin (b) (4)	10 Nov 2020 13:48:27

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '96'	Danuel Hamlin (b) (4)	10 Nov 2020 13:48:27

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User entered '%'	System	10 Nov 2020 13:48:27

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '96.5' F	Danuel Hamlin (b) (4)	10 Nov 2020 13:48:27

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:48:27

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:48:27

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:48:27

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	(b) (4) Danuel Hamlin (b) (4)	10 Nov 2020 13:48:27

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:48:27

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	(b) (4) Danuel Hamlin (b) (4)	10 Nov 2020 13:48:27

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:48:27

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:48:27

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	(b) (4) Danuel Hamlin (b) (4)	10 Nov 2020 13:48:27

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:48:27

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:48:27

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Mild (Mild)'	(b) (4) Danuel Hamlin (b) (4)	10 Nov 2020 13:48:27

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:48:27

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:48:27

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:48:27

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:48:27

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:57
Signature has been broken.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:09:57
User entered 'Day 5 (Day 5)' reason for change: Data Entry Error		29 Mar 2021 19:09:57
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Day 4 (Day 4)'	(b) (4) Danuel Hamlin (b) (4)	10 Nov 2020 13:49:14

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '05 Nov 2020'	Danuel Hamlin (b) (4)	10 Nov 2020 13:49:14

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '0'	Danuel Hamlin (b) (4)	10 Nov 2020 13:49:14

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '100'	Danuel Hamlin (b) (4)	10 Nov 2020 13:49:14

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User entered '%'	System	10 Nov 2020 13:49:14

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '97.8' F	Danuel Hamlin (b) (4)	10 Nov 2020 13:49:14

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:49:14

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:49:14

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:49:14

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:49:14

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:49:14

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:49:14

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:49:14

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:49:14

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:49:14

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:49:14

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:49:14

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:49:14

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:49:14

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:49:14

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:49:14

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:49:14

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:57
Signature has been broken.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:09:57
User entered 'Day 6 (Day 6)' reason for change: Data Entry Error		29 Mar 2021 19:09:57
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Day 5 (Day 5)'	(b) (4) Danuel Hamlin (b) (4)	10 Nov 2020 13:50:04

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '06 Nov 2020'	Danuel Hamlin (b) (4)	10 Nov 2020 13:50:04

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '0'	Danuel Hamlin (b) (4)	10 Nov 2020 13:50:04

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '98'	Danuel Hamlin (b) (4)	10 Nov 2020 13:50:04

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User entered '%'	System	10 Nov 2020 13:50:04

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:05

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '98.0' F	Danuel Hamlin (b) (4)	10 Nov 2020 13:50:04

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:50:04

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:50:04

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:50:04

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	(b) (4) Danuel Hamlin (b) (4)	10 Nov 2020 13:50:04

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	(b) (4) Danuel Hamlin (b) (4)	10 Nov 2020 13:50:04

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:50:04

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	(b) (4) Danuel Hamlin (b) (4)	10 Nov 2020 13:50:04

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:50:04

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:50:04

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:50:04

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:50:04

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:50:04

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:50:04

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	(b) (4) Danuel Hamlin (b) (4)	10 Nov 2020 13:50:04

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:50:04

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'None (None)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:50:04

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:44:05

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:20
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '02 Nov 2020'	(b) (4) Danuel Hamlin (b) (4)	10 Nov 2020 13:50:40

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:44:05

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:20
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:50:40

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:44:05

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:20
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'No (N)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:50:40

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:44:05

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:20
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '02 Nov 2020'	(b) (4) Danuel Hamlin (b) (4)	10 Nov 2020 13:50:40

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:44:05

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:20
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) Danuel Hamlin (b) (4)	10 Nov 2020 13:50:40

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:44:05

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:20
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	Danuel Hamlin (b) (4)	10 Nov 2020 13:50:40

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:44:05

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:20
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'No (N)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:50:40

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:44:05

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:20
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	Danuel Hamlin (b) (4)	10 Nov 2020 13:50:40

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:44:05

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:20
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	Danuel Hamlin (b) (4)	10 Nov 2020 13:50:40

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:44:05

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:20
User entered '0'	System	10 Nov 2020 13:50:40

US3462244

Folder: Covid-19 Assessment 01 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:44:05

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:34
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:44:35

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:44:05

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:46
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '04 Dec 2020'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:46:34

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:44:05

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:46
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '14:00'	(b) (4), (b) (6)	14 Jan 2021 18:46:34

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:44:05

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:46
User entered '04 Dec 2020 14:00'	System	14 Jan 2021 18:46:34

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:44:05

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:46
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Safety Call (Safety Call)'	(b) (4), (b) (6)	14 Jan 2021 18:46:34

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:44:05

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:46
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Jan 2021 18:46:34

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Day 1 (Day 1)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:47:51

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '03 Dec 2020'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:47:51

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '1' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:48:43
User entered '0'		14 Jan 2021 18:47:51

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:47:51

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User entered empty.	System	14 Jan 2021 18:47:51

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:47:51

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:47:51

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:47:51

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:47:51

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:47:51

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:47:51

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:47:51

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:47:51

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:47:51

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:47:51

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:47:51

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:47:51

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:47:51

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:50:30
User entered empty.		14 Jan 2021 18:47:51

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:47:51

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:47:51

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:47:51

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Day 2 (Day 2)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:48:23

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '04 Dec 2020'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:48:23

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '1' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:48:43
User entered '0'		14 Jan 2021 18:48:23

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:48:23

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User entered empty.	System	14 Jan 2021 18:48:23

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:48:23

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:48:23

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:48:23

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:48:23

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:48:23

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:52:35
User entered 'Mild (Mild)' reason for change: Data Entry Error		14 Jan 2021 18:51:35
User entered empty.		14 Jan 2021 18:48:23

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:48:23

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:48:23

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:48:23

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:48:23

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:48:23

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:48:23

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:48:23

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:48:23

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:48:23

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:52:35
User entered 'Mild (Mild)' reason for change: Data Entry Error		14 Jan 2021 18:51:35
User entered empty.		14 Jan 2021 18:48:23

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:48:23

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Day 3 (Day 3)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:48:43

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '05 Dec 2020'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:48:43

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'I'	(b) (4), (b) (6)	14 Jan 2021 18:48:43

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:48:43

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User entered empty.	System	14 Jan 2021 18:48:43

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:48:43

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:48:43

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:48:43

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:48:43

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:48:43

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:48:43

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:48:43

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:48:43

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:48:43

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:48:43

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:48:43

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:48:43

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:48:43

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:48:43

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:48:43

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:48:43

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:48:43

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Day 4 (Day 4)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:48:56

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '06 Dec 2020'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:48:56

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'I'	(b) (4), (b) (6)	14 Jan 2021 18:48:56

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:48:56

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User entered empty.	System	14 Jan 2021 18:48:56

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:48:56

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:48:56

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:48:56

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:48:56

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:48:56

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:48:56

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:48:56

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:48:56

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:48:56

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:48:56

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:48:56

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:48:56

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:48:56

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:48:56

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:48:56

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:48:56

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:48:56

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Day 5 (Day 5)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:49:22

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '07 Dec 2020'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:49:22

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '0'	(b) (4), (b) (6)	14 Jan 2021 18:49:22

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '99' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:50:02
User entered empty.		14 Jan 2021 18:49:22

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User entered '%'	System	14 Jan 2021 18:50:02
User entered empty.	System	14 Jan 2021 18:49:22

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '98.4' F reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:50:02
User entered empty.		14 Jan 2021 18:49:22

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:49:22

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:49:22

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:49:22

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:49:22

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:49:22

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:49:22

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:49:22

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:49:22

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:49:22

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:49:22

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:49:22

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:49:22

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:49:22

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:49:22

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:50:02
User entered empty.		14 Jan 2021 18:49:22

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:49:22

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Day 6 (Day 6)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:50:49
User entered empty.		14 Jan 2021 18:50:30

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Jan 2021 18:50:49
User entered '08 Dec 2020' reason for change: Data Entry Error	System	14 Jan 2021 18:50:49
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	14 Jan 2021 18:50:30
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:50:30

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '0'	(b) (4), (b) (6)	14 Jan 2021 18:50:30

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '95' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:54:23
User entered empty.		14 Jan 2021 18:50:30

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User entered '%'	System	14 Jan 2021 18:54:23
User entered empty.	System	14 Jan 2021 18:50:30

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered '97.7' F reason for change: Data Entry Error	System	14 Jan 2021 18:54:37
	(b) (4), (b) (6)	14 Jan 2021 18:54:37
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).		
User entered '97.7' (non-conformant).	System	14 Jan 2021 18:54:23
	(b) (4), (b) (6)	14 Jan 2021 18:54:23
User entered empty.		14 Jan 2021 18:50:30

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:50:30

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:50:30

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:50:30

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:50:30

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:54:23
User entered empty.		14 Jan 2021 18:50:30

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:05

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:50:30

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:50:30

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:50:30

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:50:30

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:50:30

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:50:30

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:50:30

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:50:30

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:50:30

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:54:23
User entered empty.		14 Jan 2021 18:50:30

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:50:30

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Day 7 (Day 7)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:53:53

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '09 Dec 2020'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:53:53

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '0'	(b) (4), (b) (6)	14 Jan 2021 18:53:53

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '97' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:56:08
User entered empty.		14 Jan 2021 18:53:53

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User entered '%'	System	14 Jan 2021 18:56:08
User entered empty.	System	14 Jan 2021 18:53:53

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '97.5' F reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:56:08
User entered empty.		14 Jan 2021 18:53:53

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:53:53

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:53:53

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:53:53

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:53:53

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	4 Jan 2021 18:56:08
User entered empty.		4 Jan 2021 18:53:53

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:53:53

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:53:53

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:53:53

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:53:53

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:53:53

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:53:53

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:53:53

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:53:53

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:53:53

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:56:08
User entered empty.		14 Jan 2021 18:53:53

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:53:53

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Day 8 (Day 8)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:53:53

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '10 Dec 2020'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:53:53

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '0'	(b) (4), (b) (6)	14 Jan 2021 18:53:53

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '98' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:56:45
User entered empty.		14 Jan 2021 18:53:53

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User entered '%'	System	14 Jan 2021 18:56:45
User entered empty.	System	14 Jan 2021 18:53:53

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '98.2' F reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:56:45
User entered empty.		14 Jan 2021 18:53:53

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:53:53

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:53:53

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:53:53

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:53:53

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:53:53

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:53:53

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:53:53

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:53:53

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:53:53

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:53:53

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:53:53

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:53:53

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:53:53

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:53:53

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:53:53

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:53:53

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Day 9 (Day 9)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:55:12

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '11 Dec 2020'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:55:12

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '1' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:58:32
User entered '0'		14 Jan 2021 18:55:12

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:55:12

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User entered empty.	System	14 Jan 2021 18:55:12

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:55:12

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:55:12

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:55:12

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:55:12

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:55:12

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:55:12

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:55:12

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:55:12

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:55:12

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:55:12

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:55:12

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:55:12

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:55:12

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:55:12

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:55:12

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:55:12

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:55:12

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Day 10 (Day 10)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:55:12

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '12 Dec 2020'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:55:12

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '0'	(b) (4), (b) (6)	14 Jan 2021 18:55:12

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '96' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:00:59
User entered empty.		14 Jan 2021 18:55:12

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User entered '%'	System	14 Jan 2021 19:00:59
User entered empty.	System	14 Jan 2021 18:55:12

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '98.8' F reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:00:59
User entered empty.		14 Jan 2021 18:55:12

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:55:12

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:55:12

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:55:12

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:55:12

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:55:12

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:55:12

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:55:12

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:55:12

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:55:12

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:55:12

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:55:12

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:55:12

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:55:12

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:55:12

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:55:12

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:55:12

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Day 11 (Day 11)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:55:34

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '13 Dec 2020'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:55:34

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '0'	(b) (4), (b) (6)	14 Jan 2021 18:55:34

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '99' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:01:23
User entered empty.		14 Jan 2021 18:55:34

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User entered '%'	System	14 Jan 2021 19:01:23
User entered empty.	System	14 Jan 2021 18:55:34

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '97.0' F reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:01:23
User entered empty.		14 Jan 2021 18:55:34

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:55:34

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:55:34

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:55:34

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:55:34

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:55:34

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:55:34

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:55:34

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:55:34

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:55:34

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:55:34

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:55:34

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:55:34

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:55:34

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:55:34

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:55:34

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:55:34

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Day 12 (Day 12)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:59:11

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '14 Dec 2020'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:59:11

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '1' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:02:15
User entered '0'		14 Jan 2021 18:59:11

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:59:11

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User entered empty.	System	14 Jan 2021 18:59:11

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:59:11

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:59:11

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:59:11

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:59:11

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:59:11

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:59:11

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:59:11

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:59:11

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:59:11

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:59:11

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:59:11

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:59:11

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:59:11

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:59:11

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:59:11

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:59:11

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:59:11

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:44:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Day 13 (Day 13)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:59:11

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:44:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '15 Dec 2020'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:59:11

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:44:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '0'	(b) (4), (b) (6)	14 Jan 2021 18:59:11

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:44:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '95' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:02:44
User entered empty.		14 Jan 2021 18:59:11

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:44:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User entered '%'	System	14 Jan 2021 19:02:44
User entered empty.	System	14 Jan 2021 18:59:11

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:44:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered '97.1' F reason for change: Data Entry Error	System	14 Jan 2021 19:02:50
	(b) (4), (b) (6)	14 Jan 2021 19:02:50
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).		
User entered '97.1' (non-conformant).	System	14 Jan 2021 19:02:44
	(b) (4), (b) (6)	14 Jan 2021 19:02:44
User entered empty.		14 Jan 2021 18:59:11

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:44:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:59:11

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:44:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:59:11

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:44:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:59:11

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:44:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:59:11

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:44:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:59:11

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:44:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:59:11

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:44:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:59:11

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:44:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:59:11

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:44:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:59:11

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:44:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:59:11

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:44:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:59:11

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:44:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:59:11

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:44:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:59:11

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:44:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:59:11

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:44:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:59:11

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:44:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:59:11

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:44:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Day 14 (Day 14)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:59:38

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:44:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '16 Dec 2020'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:59:38

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:44:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '0'	(b) (4), (b) (6)	14 Jan 2021 18:59:38

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:44:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '97' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:04:00
User entered empty.		14 Jan 2021 18:59:38

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:44:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User entered '%'	System	14 Jan 2021 19:04:00
User entered empty.	System	14 Jan 2021 18:59:38

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:44:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '97.7' F reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:04:00
User entered empty.		14 Jan 2021 18:59:38

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:44:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:59:38

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:44:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:59:38

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:44:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:59:38

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:44:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:59:38

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:44:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:59:38

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:44:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:59:38

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:44:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:59:38

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:44:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:59:38

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:44:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:59:38

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:44:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:59:38

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:44:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:59:38

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:44:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:59:38

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:44:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:59:38

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:44:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:59:38

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:44:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:59:38

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:44:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:59:38

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Day 15 (Day 15)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:59:50

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '17 Dec 2020'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:59:50

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '0'	(b) (4), (b) (6)	14 Jan 2021 18:59:50

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '94' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:04:31
User entered empty.		14 Jan 2021 18:59:50

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User entered '%'	System	14 Jan 2021 19:04:31
User entered empty.	System	14 Jan 2021 18:59:50

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '97.5' F reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:04:31
User entered empty.		14 Jan 2021 18:59:50

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:59:50

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:59:50

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:59:50

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:59:50

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:59:50

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:59:50

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:59:50

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:59:50

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:59:50

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:59:50

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:59:50

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:59:50

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:59:50

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:59:50

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:59:50

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:59:50

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Day 16 (Day 16)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:00:26

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '18 Dec 2020'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:00:26

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '1' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:04:45
User entered '0'		14 Jan 2021 19:00:26

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 19:00:26

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User entered empty.	System	14 Jan 2021 19:00:26

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 19:00:26

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:00:26

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 19:00:26

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 19:00:26

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:00:26

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 19:00:26

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:00:26

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 19:00:26

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 19:00:26

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 19:00:26

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 19:00:26

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 19:00:26

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:05

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 19:00:26

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 19:00:26

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 19:00:26

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 19:00:26

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 19:00:26

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Day 17 (Day 17)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:00:26

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '19 Dec 2020'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:00:26

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '0'	(b) (4), (b) (6)	14 Jan 2021 19:00:26

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '97' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:05:05
User entered empty.		14 Jan 2021 19:00:26

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User entered '%'	System	14 Jan 2021 19:05:05
User entered empty.	System	14 Jan 2021 19:00:26

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered '98.2' F reason for change: Data Entry Error	System	14 Jan 2021 19:05:15
	(b) (4), (b) (6)	14 Jan 2021 19:05:15
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).		
User entered '98.2' (non-conformant).	System	14 Jan 2021 19:05:05
	(b) (4), (b) (6)	14 Jan 2021 19:05:05
User entered empty.		14 Jan 2021 19:00:26

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 19:00:26

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 19:00:26

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 19:00:26

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 19:00:26

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 19:00:26

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:00:26

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 19:00:26

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 19:00:26

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:00:26

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:00:26

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:00:26

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 19:00:26

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 19:00:26

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 19:00:26

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 19:00:26

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:00:26

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:44:05

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '07 Dec 2020'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:47:03

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:44:05

Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:47:03

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:44:05

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:47:03

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:44:05

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '07 Dec 2020'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:47:03

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:44:05

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4), (b) (6)	14 Jan 2021 18:47:03

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:44:05

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:47:03

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:44:05

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:47:03

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:44:05

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:47:03

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:44:05

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:47:03

US3462244

Folder: Covid-19 Assessment 04 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:44:05

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:32
User entered '0'	System	14 Jan 2021 18:47:03

US3462244

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:44:05

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:54:03

US3462244

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:44:05

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
	(b) (4)	
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:54:03

US3462244

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:44:05

Date of Collection

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04,06NOV2020 is recorded under Illness Visit Day 3,5 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Jan 2021 09:55:56
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04,06NOV2020 is recorded under Illness Visit Day 3,5 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 'Confirmed, samples shipped to Viracor on 08Dec2020. Requisition ID 1F624096490, barcode number for AWB: 926434744940.' (Site from DM).		14 Jan 2021 19:20:33
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04,06NOV2020 is recorded under Illness Visit Day 3,5 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).		04 Dec 2020 07:51:29
User entered '04 Nov 2020'	Danuel Hamlin (b) (4)	10 Nov 2020 13:54:03

US3462244

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:44:05

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:54:03

US3462244

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:44:05

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
	(b) (4)	
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:54:03

US3462244

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:44:05

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
	(b) (4)	
User entered '06 Nov 2020'	Danuel Hamlin (b) (4)	10 Nov 2020 13:54:03

US3462244

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:44:05

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:54:03

US3462244

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:44:05

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:54:03

US3462244

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:44:05

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
	(b) (4)	
User entered empty.	Danuel Hamlin (b) (4)	10 Nov 2020 13:54:03

US3462244

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:44:05

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:54:03

US3462244

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:44:05

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:54:03

US3462244

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:44:05

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
	(b) (4)	
User entered empty.	Danuel Hamlin (b) (4)	10 Nov 2020 13:54:03

US3462244

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:44:05

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:54:03

US3462244

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:44:05

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Danuel Hamlin (b) (4)	10 Nov 2020 13:54:03

US3462244

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:44:05

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
	(b) (4)	
User entered empty.	Danuel Hamlin (b) (4)	10 Nov 2020 13:54:03

US3462244

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:44:05

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:54:03

US3462244

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:44:05

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Danuel Hamlin (b) (4)	10 Nov 2020 13:54:03

US3462244

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:44:05

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
	(b) (4)	
User entered empty.	Danuel Hamlin (b) (4)	10 Nov 2020 13:54:03

US3462244

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:44:05

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:54:03

US3462244

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:44:05

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Danuel Hamlin (b) (4)	10 Nov 2020 13:54:03

US3462244

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:44:05

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
	(b) (4)	
User entered empty.	Danuel Hamlin (b) (4)	10 Nov 2020 13:54:03

US3462244

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:44:05

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	18 Jan 2021 21:10:44

US3462244

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:44:05

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:10:44

US3462244

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:44:05

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '09 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:10:44

US3462244

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:44:05

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	18 Jan 2021 21:10:44

US3462244

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:44:05

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:10:44

US3462244

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:44:05

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '11 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:10:44

US3462244

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:44:05

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	18 Jan 2021 21:10:44

US3462244

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:44:05

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:10:44

US3462244

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:44:05

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '13 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:10:44

US3462244

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:44:05

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	18 Jan 2021 21:10:44

US3462244

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:44:05

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:10:44

US3462244

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:44:05

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '15 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:10:44

US3462244

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:44:05

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	18 Jan 2021 21:10:44

US3462244

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:44:05

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:10:44

US3462244

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:44:05

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:10:44

US3462244

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:44:05

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	18 Jan 2021 21:10:44

US3462244

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:44:05

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:10:44

US3462244

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:44:05

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:10:44

US3462244

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:44:05

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	18 Jan 2021 21:10:44

US3462244

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:44:05

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:10:44

US3462244

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:44:05

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:10:44

US3462244

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:39
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User closed query 'Per GCL Lab Recon: SARS-CoV-2 sample: Re-Query: Response noted, however the initiated Illness visit folder is still blank and not reflecting with corresponding SARS-CoV-2 serum sample dated 07 DEC 2020. Please review and update the data as needed, or provide clarification. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Jan 2021 10:39:40
Query 'Per GCL Lab Recon: SARS-CoV-2 sample: Re-Query: Response noted, however the initiated Illness visit folder is still blank and not reflecting with corresponding SARS-CoV-2 serum sample dated 07 DEC 2020. Please review and update the data as needed, or provide clarification. Thank you.' answered with 'Updated.' (Site from DM).		18 Jan 2021 21:11:13
User opened query 'Per GCL Lab Recon: SARS-CoV-2 sample: Re-Query: Response noted, however the initiated Illness visit folder is still blank and not reflecting with corresponding SARS-CoV-2 serum sample dated 07 DEC 2020. Please review and update the data as needed, or provide clarification. Thank you.' (Site from DM).		15 Jan 2021 14:35:04
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 07 DEC 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).		15 Jan 2021 14:35:04

US3462244

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 07 DEC 2020 is reported under illness Visit Day 1 in PPD Central lab however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' answered with 'Confirmed, second illness visit occurred on 07Dec2020, now added to EDC.' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 19:21:41
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 07 DEC 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).		16 Dec 2020 07:26:11
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:51:31

US3462244

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:39
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '02 Nov 2020'	(b) (4) Danuel Hamlin (b) (4)	10 Nov 2020 13:51:31

US3462244

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:39
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Clinic (Clinic)'	(b) (4) Danuel Hamlin (b) (4)	10 Nov 2020 13:51:31

US3462244

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:39
User entered 'SICKD1'	System	10 Nov 2020 13:51:31

US3462244

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:39
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	10 Nov 2020 13:52:32

US3462244

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:39
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '02 Nov 2020'	(b) (4) Danuel Hamlin (b) (4)	10 Nov 2020 13:52:32

US3462244

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:39
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '13:05'	(b) (4) Danuel Hamlin (b) (4)	10 Nov 2020 13:52:32

US3462244

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:39
User entered '02 Nov 2020 13:05'	System	10 Nov 2020 13:52:32

US3462244

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:39
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '158' cm	(b) (4) Danuel Hamlin (b) (4)	10 Nov 2020 13:52:32
DataPoint set to visible.	System	10 Nov 2020 13:51:31

US3462244

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:39
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '45.5' kg	(b) (4) Danuel Hamlin (b) (4)	10 Nov 2020 13:52:32
DataPoint set to visible.	System	10 Nov 2020 13:51:31

US3462244

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:39
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '36.8' C	(b) (4) Danuel Hamlin (b) (4)	10 Nov 2020 13:52:32

US3462244

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:39
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Other (Other)'	(b) (4) Danuel Hamlin (b) (4)	10 Nov 2020 13:52:32

US3462244

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:39
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Tympanic'	(b) (4) Danuel Hamlin (b) (4)	10 Nov 2020 13:52:32

US3462244

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:39
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '90'	(b) (4) Danuel Hamlin (b) (4)	10 Nov 2020 13:52:32

US3462244

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:39
User entered 'bpm'	System	10 Nov 2020 13:52:32

US3462244

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:39
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '14'	(b) (4) Danuel Hamlin (b) (4)	10 Nov 2020 13:52:32

US3462244

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:39
User entered 'breaths/min'	System	10 Nov 2020 13:52:32

US3462244

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:39
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '104'	(b) (4) Danuel Hamlin (b) (4)	10 Nov 2020 13:52:32

US3462244

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:39
User entered 'mmHg'	System	10 Nov 2020 13:52:32

US3462244

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:39
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '72'	(b) (4) Danuel Hamlin (b) (4)	10 Nov 2020 13:52:32

US3462244

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:39
User entered 'mmHg'	System	10 Nov 2020 13:52:32

US3462244

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:39

US3462244

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:39

US3462244

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:44:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:39
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	10 Nov 2020 13:53:01

US3462244

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:44:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:39
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	10 Nov 2020 13:53:01

US3462244

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 17:44:05

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:39
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	10 Nov 2020 13:53:12

US3462244

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 17:44:05

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:39
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '02 Nov 2020'	(b) (4) Danuel Hamlin (b) (4)	10 Nov 2020 13:53:12

US3462244

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:39
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:03:24

US3462244

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:39
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '07 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:03:24

US3462244

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:39
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:03:24

US3462244

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:39
User entered 'SICKD1'	System	18 Jan 2021 21:03:24

US3462244

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:39
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:08:42

US3462244

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:39
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '07 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:08:42

US3462244

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:39
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '14:35'	(b) (4), (b) (6)	18 Jan 2021 21:08:42

US3462244

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:39
User entered '07 Dec 2020 14:35'	System	18 Jan 2021 21:08:42

US3462244

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:39
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '158' cm	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:08:42
DataPoint set to visible.	System	18 Jan 2021 21:03:24

US3462244

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:39
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '45' kg	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:08:42
DataPoint set to visible.	System	18 Jan 2021 21:03:24

US3462244

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:39
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '98.4' F	(b) (4), (b) (6)	18 Jan 2021 21:08:42

US3462244

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:39
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:08:42

US3462244

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:39
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:08:42

US3462244

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:39
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '94'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:08:42

US3462244

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:39
User entered 'bpm'	System	18 Jan 2021 21:08:42

US3462244

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:39
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '16'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:08:42

US3462244

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:39
User entered 'breaths/min'	System	18 Jan 2021 21:08:42

US3462244

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:39
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '107'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:08:42

US3462244

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:39
User entered 'mmHg'	System	18 Jan 2021 21:08:42

US3462244

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:39
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '72'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:08:42

US3462244

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:39
User entered 'mmHg'	System	18 Jan 2021 21:08:42

US3462244

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:39

US3462244

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:05

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:39

US3462244

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:44:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:39
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:09:01

US3462244

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:44:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:39
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '07 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:09:01

US3462244

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 17:44:05

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:39
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:09:11

US3462244

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 17:44:05

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:39
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '07 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:09:11

US3462244

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

Form: Visit Date

Generated On: 09 Jun 2021 17:44:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:13:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 17:50:48

US3462244

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

Form: Visit Date

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:13:50
User entered '22 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 17:50:48

US3462244

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

Form: Visit Date

Generated On: 09 Jun 2021 17:44:05

[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 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:13:50
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 17:50:48

US3462244

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

Form: Visit Date

Generated On: 09 Jun 2021 17:44:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User entered 'UNBLND_DECIDE'	System	22 Feb 2021 17:50:48

US3462244

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

Form: Unblinding

Generated On: 09 Jun 2021 17:44:05

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:13:50
User entered '22 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 17:51:25

US3462244

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

Form: Unblinding

Generated On: 09 Jun 2021 17:44:05

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:13:50
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 05:48:08

US3462244

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

Form: Unblinding

Generated On: 09 Jun 2021 17:44:05

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:13:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 17:51:25

US3462244

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

Form: Unblinding

Generated On: 09 Jun 2021 17:44:05

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:13:50
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 05:48:08

US3462244

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

Form: Unblinding

Generated On: 09 Jun 2021 17:44:05

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:13:50
User entered '22 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 17:51:25

US3462244

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

Form: Unblinding

Generated On: 09 Jun 2021 17:44:05

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:13:50
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 17:51:25

US3462244

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

Form: Unblinding

Generated On: 09 Jun 2021 17:44:05

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:13:50
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 17:51:25

US3462244

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

Form: Unblinding

Generated On: 09 Jun 2021 17:44:05

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:13:50
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 17:51:25

US3462244

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

Form: Unblinding

Generated On: 09 Jun 2021 17:44:05

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:13:50
User closed query 'Actual dose 1 and Actual dose 2 are both recorded as mRNA-1273, however, 'Will participant receive mRNA-1273?' is Yes. Please reconcile.' (Site from System).	(b) (4)	
Query 'Actual dose 1 and Actual dose 2 are both recorded as mRNA-1273, however, 'Will participant receive mRNA-1273?' is Yes. Please reconcile.' answered by data change (Site from System).	System	22 Feb 2021 17:51:30
User entered 'No (N)' reason for change: Data Entry Error	System	22 Feb 2021 17:51:30
User opened query 'Actual dose 1 and Actual dose 2 are both recorded as mRNA-1273, however, 'Will participant receive mRNA-1273?' is Yes. Please reconcile.' (Site from System).	(b) (4), (b) (6)	22 Feb 2021 17:51:30
User entered 'Yes (Y)'	System	22 Feb 2021 17:51:25
	(b) (4), (b) (6)	22 Feb 2021 17:51:25

US3462244

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

Form: Unblinding

Generated On: 09 Jun 2021 17:44:05

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User entered empty.	System	22 Feb 2021 17:51:25

US3462244

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

Form: Unblinding

Generated On: 09 Jun 2021 17:44:05

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User entered empty.	System	22 Feb 2021 17:51:25

US3462244

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:44:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:13:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 17:51:40

US3462244

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:44:05

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:13:50
User entered '22 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 17:51:40

US3462244

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:44:05

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:13:50
User entered '11:48'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 17:51:40

US3462244

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:44:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User entered '22 Jan 2021 11:48'	System	22 Feb 2021 17:51:40

US3462244

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:44:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:13:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 17:51:51

US3462244

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:13:50
User entered '22 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 17:51:51

US3462244

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:44:05

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:13:50
User entered '11:34'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 17:51:51

US3462244

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:44:05

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:32
User entered '22 Jan 2021 11:34'	System	22 Feb 2021 17:51:51

US3462244

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:44:05

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	10 Nov 2020 13:54:15

US3462244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:05

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:17:25

US3462244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:05

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:17:25
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User closed query 'Per MM: Please update AE to provide symptoms.' (Site from DM).	(b) (4)	
User closed query 'Per MM, please confirm if this is not COVID-19. If not, update the AE term to reflect the causative organism, if known.' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 21:02:14
Query 'Per MM: Please update AE to provide symptoms.' answered with 'Symptoms added under AE "Narrative"' (Site from DM).		15 Jan 2021 21:01:23
Query 'Per MM, please confirm if this is not COVID-19. If not, update the AE term to reflect the causative organism, if known.' answered with 'Confirmed, this event NOT Covid-19. Causative organism unknown.' (Site from DM).		14 Jan 2021 18:44:04
User opened query 'Per MM, please confirm if this is not COVID-19. If not, update the AE term to reflect the causative organism, if known.' (Site from DM).		14 Jan 2021 18:40:45
User opened query 'Per MM: Please update AE to provide symptoms.' (Site from DM).		14 Dec 2020 16:58:21
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Upper respiratory tract infection, LLT: Upper respiratory tract infection - version MedDRA\23.0.	Coder Import (b) (4)	20 Nov 2020 09:27:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	10 Nov 2020 13:57:31
Data point term sent to Coder		
User entered 'Upper Respiratory Tract Infection'	Coder Import (b) (4)	10 Nov 2020 13:57:31
	(b) (4)	
	System	10 Nov 2020 13:56:25
	Danuel Hamlin (b) (4)	10 Nov 2020 13:55:43

US3462244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:17:25
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'No (N)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:55:43

US3462244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:17:25
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'No (N)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:55:43

US3462244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:17:25
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	10 Nov 2020 13:55:43

US3462244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:05

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:17:25
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '31 Oct 2020'	(b) (4) Danuel Hamlin (b) (4)	10 Nov 2020 13:55:43

US3462244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:05

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:17:25
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User closed query 'Per CDM: Per previous query, this AE did not start within 24 hours of receiving IP, therefore the Start Time (09:00) is not required. Please delete start time.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 07:30:13
Query 'Per CDM: Per previous query, this AE did not start within 24 hours of receiving IP, therefore the Start Time (09:00) is not required. Please delete start time.' answered with 'Corrected' (Site from DM).		18 Nov 2020 21:46:41
User entered empty; reason for change Data Entry Error		18 Nov 2020 21:46:31
User opened query 'Per CDM: Per previous query, this AE did not start within 24 hours of receiving IP, therefore the Start Time (09:00) is not required. Please delete start time.' (Site from DM).		18 Nov 2020 11:05:44
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).		18 Nov 2020 11:04:30
Query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' answered with 'Time is unknown' (Site from System).	Danuel Hamlin (b) (4)	10 Nov 2020 13:56:01
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	10 Nov 2020 13:55:43
User entered '09:00'	Danuel Hamlin (b) (4)	10 Nov 2020 13:55:43

US3462244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:05

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:17:25
User entered empty.	System	18 Nov 2020 21:46:31
User entered '31 Oct 2020 09:00'	System	10 Nov 2020 13:55:43

US3462244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:17:25
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'No (N)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:55:43

US3462244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:17:25
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '06 Nov 2020'	Danuel Hamlin (b) (4)	10 Nov 2020 13:55:43

US3462244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:05

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:17:25
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	Danuel Hamlin (b) (4)	10 Nov 2020 13:55:43

US3462244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:05

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:17:25
User entered empty.	System	10 Nov 2020 13:55:43

US3462244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:05

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:17:25
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Danuel Hamlin (b) (4)	10 Nov 2020 13:55:43

US3462244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:17:25
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'No (N)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:55:43

US3462244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:05

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:17:25
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '0'	Danuel Hamlin (b) (4)	10 Nov 2020 13:55:43

US3462244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:05

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:17:25
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '0'	Danuel Hamlin (b) (4)	10 Nov 2020 13:55:43

US3462244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:17:25
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '0'	Danuel Hamlin (b) (4)	10 Nov 2020 13:55:43

US3462244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:17:25
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	Danuel Hamlin (b) (4)	10 Nov 2020 13:55:43

US3462244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:05

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:17:25
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	Danuel Hamlin (b) (4)	10 Nov 2020 13:55:43

US3462244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:05

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:17:25
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	Danuel Hamlin (b) (4)	10 Nov 2020 13:55:43

US3462244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:17:25
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	Danuel Hamlin (b) (4)	10 Nov 2020 13:55:43

US3462244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:17:25
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '0'	Danuel Hamlin (b) (4)	10 Nov 2020 13:55:43

US3462244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:17:25
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '0'	Danuel Hamlin (b) (4)	10 Nov 2020 13:55:43

US3462244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:05

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:17:25
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '0'	Danuel Hamlin (b) (4)	10 Nov 2020 13:55:43

US3462244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:17:25
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Not Related (NOT RELATED)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:55:43

US3462244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:17:25
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Not Related (NOT RELATED)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:55:43

US3462244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:05

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:17:25
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Danuel Hamlin (b) (4)	10 Nov 2020 13:55:43

US3462244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:05

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:17:25
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'I'	Danuel Hamlin (b) (4)	10 Nov 2020 13:55:43

US3462244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:17:25
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '0'	Danuel Hamlin (b) (4)	10 Nov 2020 13:55:43

US3462244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:17:25
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '0'	Danuel Hamlin (b) (4)	10 Nov 2020 13:55:43

US3462244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:05

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:17:25
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Danuel Hamlin (b) (4)	10 Nov 2020 13:55:43

US3462244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:05

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:17:25
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	10 Nov 2020 13:55:43

US3462244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:05

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:17:25
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Patient's initial symptoms were mild cough, sore throat, fatigue and headache.' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Jan 2021 18:43:42
User entered empty.	Danuel Hamlin (b) (4)	10 Nov 2020 13:55:43

US3462244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:05

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:17:25
User entered '0'	System	10 Nov 2020 13:55:43

US3462244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:05

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:17:25
User entered '0'	System	10 Nov 2020 13:55:43

US3462244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:05

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:17:25

US3462244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:05

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:48

US3462244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:05

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:48
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:57
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Gastroenteritis, LLT: Gastroenteritis - version MedDRA\\23.0.	Coder Import (b) (4)	22 Feb 2021 20:12:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Feb 2021 20:12:02
Data point term sent to Coder	System	22 Feb 2021 19:55:37
User entered 'Gastroenteritis'	(b) (4), (b) (6)	22 Feb 2021 19:55:33

US3462244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:48
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Feb 2021 19:55:33

US3462244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:48
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:57
User entered 'No (N)'	(b) (4), (b) (6)	22 Feb 2021 19:55:33

US3462244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:48
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:57
User entered 'No (N)'	(b) (4), (b) (6)	22 Feb 2021 19:55:33

US3462244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:05

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:48
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:57
User entered '03 Dec 2020'	(b) (4), (b) (6)	22 Feb 2021 19:55:33

US3462244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:05

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:48
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:57
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 19:55:33

US3462244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:05

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:48
User entered empty.	System	22 Feb 2021 19:55:33

US3462244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:48
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:57
User entered 'No (N)'	(b) (4), (b) (6)	22 Feb 2021 19:55:33

US3462244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:48
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:57
User entered '19 Dec 2020'	(b) (4), (b) (6)	22 Feb 2021 19:55:33

US3462244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:05

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:48
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:57
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 19:55:33

US3462244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:05

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:48
User entered empty.	System	22 Feb 2021 19:55:33

US3462244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:05

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:48
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:57
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	22 Feb 2021 19:55:33

US3462244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:48
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:57
User entered 'No (N)'	(b) (4), (b) (6)	22 Feb 2021 19:55:33

US3462244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:05

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:48
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:57
User entered '0'	(b) (4), (b) (6)	22 Feb 2021 19:55:33

US3462244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:05

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:48
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:57
User entered '0'	(b) (4), (b) (6)	22 Feb 2021 19:55:33

US3462244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:48
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:57
User entered '0'	(b) (4), (b) (6)	22 Feb 2021 19:55:33

US3462244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:48
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:57
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 19:55:33

US3462244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:05

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:48
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:57
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 19:55:33

US3462244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:05

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:48
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:57
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 19:55:33

US3462244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:48
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:57
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 19:55:33

US3462244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:48
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:57
User entered '0'	(b) (4), (b) (6)	22 Feb 2021 19:55:33

US3462244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:48
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:57
User entered '0'	(b) (4), (b) (6)	22 Feb 2021 19:55:33

US3462244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:05

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:48
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:57
User entered '0'	(b) (4), (b) (6)	22 Feb 2021 19:55:33

US3462244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:48
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:57
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:55:33

US3462244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:48
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:57
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:55:33

US3462244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:05

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:48
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:57
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	22 Feb 2021 19:55:33

US3462244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:05

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:48
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:57
User entered '0'	(b) (4), (b) (6)	22 Feb 2021 19:55:33

US3462244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:48
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:57
User entered 'I'	(b) (4), (b) (6)	22 Feb 2021 19:55:33

US3462244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:48
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:57
User entered '0'	(b) (4), (b) (6)	22 Feb 2021 19:55:33

US3462244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:05

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:48
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:57
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	22 Feb 2021 19:55:33

US3462244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:05

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:48
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:57
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 19:55:33

US3462244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:05

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:48
User closed query 'Per DM CLR: Narrative = PATIENT REPORTED GI SYMPTOMS BEGINNING ON 07DEC2020 AND RESOLVED BY 10DEC2020. However, this does not correspond to the recorded start and end date of this AE. Please review and reconcile data as appropriate. ' (Site from DM). User signature succeeded.	(b) (4)	30 Mar 2021 13:11:06
Query 'Per DM CLR: Narrative = PATIENT REPORTED GI SYMPTOMS BEGINNING ON 07DEC2020 AND RESOLVED BY 10DEC2020. However, this does not correspond to the recorded start and end date of this AE. Please review and reconcile data as appropriate. ' answered with 'Corrected the AE start date to date of symptom onset. 10DEC2020 was date of symptom resolution, but negative Covid-19 lab confirmation was not received until 19DEC2020, hence AE end date later than symptom resolution.' (Site from DM). User entered 'PATIENT REPORTED GI SYMPTOMS BEGINNING ON 03DEC2020 AND RESOLVED BY 10DEC2020. HOWEVER, DUE TO LABORATORY DELAYS WITH TESTING THE NASAL SWAB, NEGATIVE COVID-19 RESULT WAS NOT RETURNED UNTIL 19DEC2020.' reason for change: Data Entry Error User opened query 'Per DM CLR: Narrative = PATIENT REPORTED GI SYMPTOMS BEGINNING ON 07DEC2020 AND RESOLVED BY 10DEC2020. However, this does not correspond to the recorded start and end date of this AE. Please review and reconcile data as appropriate. ' (Site from DM). User entered 'Patient reported GI symptoms beginning on 07DEC2020 and resolved by 10DEC2020. However, due to laboratory delays with testing the nasal swab, negative Covid-19 result was not returned until 19DEC2020.'	Gregg Lucksinger (b) (4) (b) (4) (b) (4), (b) (6)	30 Mar 2021 00:58:57 29 Mar 2021 19:04:10 29 Mar 2021 19:03:55 01 Mar 2021 10:05:51 22 Feb 2021 19:55:33

US3462244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:05

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:48
User entered '0'	System	22 Feb 2021 19:55:33

US3462244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:05

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:48
User entered 'I'	System	22 Feb 2021 19:55:33

US3462244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:05

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:48

US3462244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:05

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:14:11
User entered 'USA-US093-2021-mRNA-1273-P301000010'	System	16 Apr 2021 13:14:05
User entered 'New'	(b) (4), (b) (6)	16 Apr 2021 13:14:05

US3462244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:05

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Pregnancy, puerperium and perinatal conditions, HLGT: Pregnancy, labour, delivery and postpartum conditions, HLT: Normal pregnancy, labour and delivery, PT: Pregnancy, LLT: Pregnancy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Apr 2021 08:37:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Apr 2021 08:37:31
User signature succeeded.	Gregg Lucksinger (b) (4) (b) (4)	16 Apr 2021 22:56:20
Data point term sent to Coder	System	15 Apr 2021 21:19:23
User entered 'Pregnancy on study'	(b) (4), (b) (6) (b) (4)	15 Apr 2021 21:19:04

US3462244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:19:04

US3462244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:19:04

US3462244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:19:04

US3462244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
User entered '12 Apr 2021'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:19:04

US3462244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:05

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:19:04

US3462244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:05

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 21:19:04

US3462244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:05

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:19:04

US3462244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:05

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:19:04

US3462244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:05

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:19:04

US3462244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:05

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 21:19:04

US3462244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:05

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:19:04

US3462244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:19:04

US3462244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:05

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:19:04

US3462244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:19:04

US3462244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:19:04

US3462244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 21:19:04

US3462244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:05

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:19:04

US3462244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:05

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:19:04

US3462244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:19:04

US3462244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:19:04

US3462244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:19:04

US3462244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
User entered 'I'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:19:04

US3462244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:19:04

US3462244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:19:04

US3462244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:05

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:19:04

US3462244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:05

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
User entered '1'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:19:04

US3462244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:19:04

US3462244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:19:04

US3462244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:05

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
User entered 'Unknown (UNKNOWN)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:19:04

US3462244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:05

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:19:04

US3462244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:05

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
User entered 'Patient contacted site to inform of positive pregnancy test dated 12APR2021. Patient noticed delayed menses, increased frequency of urination, and abdominal swelling leading to her visiting her PCP. Patient had an IUD inserted in 2018 and removed in Dec2020, but did not inform site of IUD removal. Patient reported waiting 3 months after Day 29 before removing IUD, which corresponds to protocol inclusion criteria for FOCBP.'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:19:04

US3462244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:05

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Apr 2021 21:19:04

US3462244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:44:05

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Apr 2021 21:19:04

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:13:50
User closed query 'Per DM CLR: Per Diary Dose 2 Day 2, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:31:24
Query 'Per DM CLR: Per Diary Dose 2 Day 2, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' answered with 'updated' (Site from DM).		22 Feb 2021 17:47:14
User opened query 'Per DM CLR: Per Diary Dose 2 Day 2, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).		18 Feb 2021 21:57:18
User entered 'Yes (Y)'		20 Aug 2020 21:29:42

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:44:05

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: DESVENLAFAXINE SUCCINATE, PRODUCTSYNONYM: PRISTIQ - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	07 Sep 2020 17:34:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Sep 2020 17:34:44
Data point term sent to Coder	System	20 Aug 2020 21:30:42
User entered 'prestique'	(b) (4), (b) (6)	20 Aug 2020 21:30:41

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:44:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:30:41

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:44:05

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User closed query 'Per DM CLR: Please note that 'depression' is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:20:35
Query 'Per DM CLR: Please note that 'depression' is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' answered with 'Added' (Site from DM).	Danuel Hamlin (b) (4)	04 Nov 2020 00:01:00
User opened query 'Per DM CLR: Please note that 'depression' is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 14:54:39
User entered 'anxiety/depression'		20 Aug 2020 21:30:41

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:44:05

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:57
Signature has been broken.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 17:48:12
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '100'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:30:41

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:44:05

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:30:41

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:44:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:30:41

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:44:05

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:30:41

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:44:05

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:57
Signature has been broken.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 17:48:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:30:41

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:44:05

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:30:41

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:44:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:30:41

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:44:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 05:37:56
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 'Confirmed start date; currently taking medication' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 21:30:50
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	20 Aug 2020 21:30:41
User entered 'un UNK 2018'	(b) (4), (b) (6)	20 Aug 2020 21:30:41

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:44:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:30:41

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:44:05

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:30:41

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:44:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:30:41

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:44:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:30:41

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:44:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 21:30:41

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:44:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 21:30:41

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:44:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 21:30:41

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:44:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:10
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: BUPROPION HYDROCHLORIDE, PRODUCTSYNONYM: WELLBUTRIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	21 Aug 2020 08:35:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 08:35:11
Data point term sent to Coder	System	20 Aug 2020 21:32:43
User entered 'WELLBUTRIN'	(b) (4), (b) (6)	20 Aug 2020 21:31:53

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:44:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:10
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:31:53

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:44:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:10
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User closed query 'Per DM CLR: Please note that 'depression' is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:20:42
Query 'Per DM CLR: Please note that 'depression' is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' answered with 'Added' (Site from DM).	Danuel Hamlin (b) (4)	04 Nov 2020 00:00:39
User opened query 'Per DM CLR: Please note that 'depression' is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 14:54:49
User entered 'Anxiety/depression'		20 Aug 2020 21:31:53

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:44:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:10
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '300'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:31:53

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:44:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:10
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:31:53

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:44:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:10
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:31:53

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:44:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:10
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:31:53

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:44:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:10
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:31:53

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:44:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:10
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:31:53

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:44:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:10
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:31:53

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:44:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:10
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 05:37:56
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 'Confirmed start date; currently taking medication' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 21:31:58
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	20 Aug 2020 21:31:53
User entered 'un May 2020'	(b) (4), (b) (6)	20 Aug 2020 21:31:53

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:44:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:10
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:31:53

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:44:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:10
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Danuel Hamlin (b) (4)	03 Nov 2020 23:49:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 21:31:53

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:44:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:10
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '01 Oct 2020' reason for change: Data Entry Error	(b) (4) Danuel Hamlin (b) (4)	03 Nov 2020 23:49:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 21:31:53

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:44:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:10
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:31:53

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:44:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:10
User entered '1'	System	20 Aug 2020 21:31:53

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:44:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:10
User entered '1'	System	20 Aug 2020 21:31:53

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:44:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:10
User entered '804 (804)'	System	20 Aug 2020 21:31:53

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:44:05

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: VALACICLOVIR HYDROCHLORIDE, PRODUCTSYNONYM: VALTREX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Aug 2020 21:34:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Aug 2020 21:34:35
Data point term sent to Coder	System	20 Aug 2020 21:33:46
User entered 'Valtrex'	(b) (4), (b) (6)	20 Aug 2020 21:32:50

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:44:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:32:50

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:44:05

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'HSV-1'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:32:50

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:44:05

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '500'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:32:50

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:44:05

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:32:50

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:44:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:32:50

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:44:05

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:32:50

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:44:05

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:32:50

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:44:05

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:32:50

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:44:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:32:50

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:44:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 05:37:56
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 'Confirmed start date; currently taking medication' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 21:32:57
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	20 Aug 2020 21:32:50
User entered 'un UNK 2018'	(b) (4), (b) (6)	20 Aug 2020 21:32:50

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:44:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:32:50

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:44:05

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:32:50

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:44:05

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:32:50

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:44:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:32:50

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:44:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 21:32:50

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:44:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 21:32:50

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:44:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 21:32:50

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:44:05

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:19
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, consider recording an AE of Worsening DEPRESSION/ANXIETY; update Con Med indication or provide clarification. ' (Site from DM). Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, consider recording an AE of Worsening DEPRESSION/ANXIETY; update Con Med indication or provide clarification. ' answered with 'Dosage was reduced not increased, patient condition was not worsening.' (Site from DM). User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, consider recording an AE of Worsening DEPRESSION/ANXIETY; update Con Med indication or provide clarification. ' (Site from DM). User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: BUPROPION HYDROCHLORIDE, PRODUCTSYNONYM: WELLBUTRIN - version WHODrug-Global-B3\\202003. User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. Data point term sent to Coder User entered 'Wellbutrin'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 03:00:46 26 Jan 2021 19:08:09 22 Jan 2021 11:32:08 03 Nov 2020 23:52:29 03 Nov 2020 23:52:29 03 Nov 2020 23:51:28 03 Nov 2020 23:50:56

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:44:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:19
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	03 Nov 2020 23:50:56

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:44:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:19
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Depression/Anxiety'	(b) (4) Danuel Hamlin (b) (4)	03 Nov 2020 23:50:56

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:44:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:19
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '100'	(b) (4) Danuel Hamlin (b) (4)	03 Nov 2020 23:50:56

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:44:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:19
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'mg (mg)'	(b) (4) Danuel Hamlin (b) (4)	03 Nov 2020 23:50:56

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:44:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:19
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	03 Nov 2020 23:50:56

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:44:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:19
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'once daily (QD)'	Danuel Hamlin (b) (4)	03 Nov 2020 23:50:56

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:44:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:19
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	03 Nov 2020 23:50:56

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:44:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:19
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Oral (ORAL)'	(b) (4) Danuel Hamlin (b) (4)	03 Nov 2020 23:50:56

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:44:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:19
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	03 Nov 2020 23:50:56

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:44:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:19
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '02 Oct 2020'	(b) (4) Danuel Hamlin (b) (4)	03 Nov 2020 23:50:56

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:44:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:19
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	03 Nov 2020 23:50:56

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:44:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:19
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:50:23
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	03 Nov 2020 23:50:56

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:44:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:19
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '18 Oct 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:50:23
User entered empty.	Danuel Hamlin (b) (4)	03 Nov 2020 23:50:56

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:44:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:19
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User closed query 'Per CDM RQ: Response noted. However this field has not been updated. Please complete. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 07:31:05
Query 'Per CDM RQ: Response noted. However this field has not been updated. Please complete. ' answered with 'Corrected' (Site from DM).		18 Nov 2020 21:50:40
User entered 'No (N)' reason for change: Data Entry Error		18 Nov 2020 21:50:23
User closed query 'Data is required. Please complete.' (Site from System).		12 Nov 2020 20:22:14
User opened query 'Per CDM RQ: Response noted. However this field has not been updated. Please complete. ' (Site from DM).		12 Nov 2020 20:22:12
Query 'Data is required. Please complete.' answered with 'Added' (Site from System).	Danuel Hamlin (b) (4)	04 Nov 2020 00:02:13
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 23:50:56
User entered empty.	Danuel Hamlin (b) (4)	03 Nov 2020 23:50:56

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:44:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:19
User entered '1'	System	03 Nov 2020 23:50:56

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:44:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:19
User entered '1'	System	03 Nov 2020 23:50:56

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:44:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:19
User entered '804 (804)'	System	03 Nov 2020 23:50:56

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:44:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:32
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 17:49:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 17:49:00
Data point term sent to Coder	System	22 Feb 2021 17:48:45
Coding entries removed.	(b) (4), (b) (6)	22 Feb 2021 17:47:46
User signature succeeded.	Gregg Lucksinger (b) (4) (b) (4)	19 Feb 2021 20:17:52
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 00:57:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 00:57:27
Data point term sent to Coder	System	04 Nov 2020 00:57:18
User entered 'Tylenol'	Danuel Hamlin (b) (4)	04 Nov 2020 00:56:36

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:44:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 00:56:36

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:44:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:32
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:57
Query 'Per DM CLR: Please note that there is no HEADACHE recorded in AE or Dairy event that matches this Con med indication. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRF. Else, provide clarification.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:36:50
User opened query 'Per DM CLR: Please note that there is no HEADACHE recorded in AE or Dairy event that matches this Con med indication. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRF. Else, provide clarification.' (Site from DM).		01 Mar 2021 14:36:38
Signature has been broken.		22 Feb 2021 17:47:46
User entered 'INJECTION SITE PAIN/ Headache' reason for change: Data Entry Error		22 Feb 2021 17:47:46
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Injection Site Pain'	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 00:56:36

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:44:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '650'	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 00:56:36

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:44:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'mg (mg)'	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 00:56:36

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:44:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 00:56:36

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:44:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'as needed (PRN)'	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 00:56:36

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:44:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 00:56:36

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:44:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Oral (ORAL)'	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 00:56:36

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:44:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 00:56:36

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '19 Aug 2020'	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 00:56:36

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:44:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 00:56:36

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:44:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 00:56:36

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:44:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '20 Aug 2020'	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 00:56:36

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:44:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 00:56:36

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:44:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:32
User entered empty.	System	04 Nov 2020 00:56:36

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:44:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:32
User entered empty.	System	04 Nov 2020 00:56:36

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:44:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:32
User entered empty.	System	04 Nov 2020 00:56:36

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:44:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:36
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 17:49:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 17:49:01
Data point term sent to Coder	System	22 Feb 2021 17:48:45
Coding entries removed.	(b) (4), (b) (6)	22 Feb 2021 17:47:58
User signature succeeded.	Gregg Lucksinger (b) (4) (b) (4)	19 Feb 2021 20:17:52
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 00:59:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 00:59:27
Data point term sent to Coder	System	04 Nov 2020 00:58:18
User entered 'Tylenol'	Danuel Hamlin (b) (4)	04 Nov 2020 00:58:13

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:44:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:36
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 00:58:13

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:44:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:36
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN AT INJECTION SITE/ HEADACHE is considered a solicited local or systemic adverse reaction and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE/ HEADACHE did not meet the AE reporting criteria. ' (Site from DM).		30 Mar 2021 13:10:58
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:57
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN AT INJECTION SITE/ HEADACHE is considered a solicited local or systemic adverse reaction and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE/ HEADACHE did not meet the AE reporting criteria. ' answered with 'Confirmed, solicited adverse reaction of PAIN AT INJECTION SITE/ HEADACHE did not meet the AE reporting criteria.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:05:52

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:44:05

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN AT INJECTION SITE/ HEADACHE is considered a solicited local or systemic adverse reaction and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE/ HEADACHE did not meet the AE reporting criteria. ' (Site from DM). Signature has been broken.	(b) (4), (b) (6)	01 Mar 2021 14:38:18
		22 Feb 2021 17:47:58
User entered 'INJECTION SITE PAIN/ Headache' reason for change: Data Entry Error		22 Feb 2021 17:47:58
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Injection Site Pain'	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 00:58:13

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:44:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:36
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '650'	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 00:58:13

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:44:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:36
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'mg (mg)'	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 00:58:13

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:44:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:36
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 00:58:13

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:44:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:36
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'as needed (PRN)'	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 00:58:13

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:44:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:36
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 00:58:13

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:44:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:36
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Oral (ORAL)'	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 00:58:13

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:44:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:36
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 00:58:13

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:44:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:36
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '16 Sep 2020'	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 00:58:13

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:44:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:36
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 00:58:13

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:44:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:36
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 00:58:13

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:44:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:36
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered '17 Sep 2020'	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 00:58:13

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:44:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:36
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:17:52
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 00:58:13

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:44:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:36
User entered empty.	System	04 Nov 2020 00:58:13

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:44:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:36
User entered empty.	System	04 Nov 2020 00:58:13

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:44:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:36
User entered empty.	System	04 Nov 2020 00:58:13

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:44:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:57
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: ANTIPROPULSIVES, ATC: ANTIPROPULSIVES, PRODUCT: LOPERAMIDE HYDROCHLORIDE, PRODUCTSYNONYM: IMODIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Mar 2021 12:13:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	02 Mar 2021 12:13:43
Data point term sent to Coder	System	22 Feb 2021 19:57:40
User entered 'Immodium'	(b) (4), (b) (6)	22 Feb 2021 19:56:58

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:44:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:57
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:57
User entered 'No (N)'	(b) (4), (b) (6)	22 Feb 2021 19:56:58

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:44:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:57
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:57
User entered 'GASTROENTERITIS, diarrhea' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:57:17
User entered 'Gastroenteritis'		22 Feb 2021 19:56:58

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:44:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:57
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:57
User entered '4'	(b) (4), (b) (6)	22 Feb 2021 19:56:58

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:44:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:57
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:57
User entered 'mg (mg)'	(b) (4), (b) (6)	22 Feb 2021 19:56:58

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:44:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:57
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:57
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 19:56:58

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:44:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:57
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:57
User entered 'as needed (PRN)'	(b) (4), (b) (6)	22 Feb 2021 19:56:58

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:44:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:57
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:57
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 19:56:58

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:44:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:57
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:57
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	22 Feb 2021 19:56:58

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:44:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:57
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:57
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 19:56:58

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:44:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:57
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:57
User entered '03 Dec 2020'	(b) (4), (b) (6)	22 Feb 2021 19:56:58

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:44:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:57
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:57
User entered '0'	(b) (4), (b) (6)	22 Feb 2021 19:56:58

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:44:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:57
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:57
User entered 'No (N)'	(b) (4), (b) (6)	22 Feb 2021 19:56:58

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:44:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:57
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:57
User entered '03 Dec 2020'	(b) (4), (b) (6)	22 Feb 2021 19:56:58

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:44:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:57
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:57
User entered 'No (N)'	(b) (4), (b) (6)	22 Feb 2021 19:56:58

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:44:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:57
User entered empty.	System	22 Feb 2021 19:56:58

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:44:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:57
User entered empty.	System	22 Feb 2021 19:56:58

US3462244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:44:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:57
User entered empty.	System	22 Feb 2021 19:56:58

US3462244

Folder: SAE USA-US093-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:05

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:14:21
User entered 'USA-US093-2021-MRNA-1273-P301000010'	System	16 Apr 2021 13:14:05

US3462244

Folder: SAE USA-US093-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:05

Serious

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:14:21
User entered 'Yes (Y)'	System	16 Apr 2021 13:14:05

US3462244

Folder: SAE USA-US093-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:05

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:14:21
User entered 'No (N)'	System	16 Apr 2021 13:14:05

US3462244

Folder: SAE USA-US093-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:14:21
User entered 'No (N)'	System	16 Apr 2021 13:14:05

US3462244

Folder: SAE USA-US093-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:14:21
User entered 'No (N)'	System	16 Apr 2021 13:14:05

US3462244

Folder: SAE USA-US093-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:14:21
User entered 'No (N)'	System	16 Apr 2021 13:14:05

US3462244

Folder: SAE USA-US093-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:14:21
User entered 'No (N)'	System	16 Apr 2021 13:14:05

US3462244

Folder: SAE USA-US093-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:14:21
User entered 'Yes (Y)'	System	16 Apr 2021 13:14:05

US3462244

Folder: SAE USA-US093-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:14:21
User entered 'Gregg'	System	16 Apr 2021 13:14:05

US3462244

Folder: SAE USA-US093-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:14:21
User entered 'Lucksinger'	System	16 Apr 2021 13:14:05

US3462244

Folder: SAE USA-US093-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:05

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:14:21
User entered '1900 Cypress Creek Rd'	System	16 Apr 2021 13:14:05

US3462244

Folder: SAE USA-US093-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:05

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:14:21
User entered 'Cedar Park'	System	16 Apr 2021 13:14:05

US3462244

Folder: SAE USA-US093-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:05

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:14:21
User entered 'TX'	System	16 Apr 2021 13:14:05

US3462244

Folder: SAE USA-US093-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:05

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:14:21
User entered '78613'	System	16 Apr 2021 13:14:05

US3462244

Folder: SAE USA-US093-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:05

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
User entered 'US'	(b) (4) System	16 Apr 2021 13:14:31

US3462244

Folder: SAE USA-US093-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Apr 2021 13:14:31

US3462244

Folder: SAE USA-US093-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:05

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:14:21
User entered 'USA-US093-2021-MRNA-1273-P301000010'	System	16 Apr 2021 13:14:05

US3462244

Folder: SAE USA-US093-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:05

Serious

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:14:21
User entered 'Yes (Y)'	System	16 Apr 2021 13:14:05

US3462244

Folder: SAE USA-US093-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:05

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:14:21
User entered 'No (N)'	System	16 Apr 2021 13:14:05

US3462244

Folder: SAE USA-US093-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:14:21
User entered 'No (N)'	System	16 Apr 2021 13:14:05

US3462244

Folder: SAE USA-US093-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:14:21
User entered 'No (N)'	System	16 Apr 2021 13:14:05

US3462244

Folder: SAE USA-US093-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:14:21
User entered 'No (N)'	System	16 Apr 2021 13:14:05

US3462244

Folder: SAE USA-US093-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:14:21
User entered 'No (N)'	System	16 Apr 2021 13:14:05

US3462244

Folder: SAE USA-US093-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:14:21
User entered 'Yes (Y)'	System	16 Apr 2021 13:14:05

US3462244

Folder: SAE USA-US093-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:14:21
User entered 'Gregg'	System	16 Apr 2021 13:14:05

US3462244

Folder: SAE USA-US093-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:14:21
User entered 'Lucksinger'	System	16 Apr 2021 13:14:05

US3462244

Folder: SAE USA-US093-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:05

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:14:21
User entered '1900 Cypress Creek Rd'	System	16 Apr 2021 13:14:05

US3462244

Folder: SAE USA-US093-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:05

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:14:21
User entered 'Cedar Park'	System	16 Apr 2021 13:14:05

US3462244

Folder: SAE USA-US093-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:05

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:14:21
User entered 'TX'	System	16 Apr 2021 13:14:05

US3462244

Folder: SAE USA-US093-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:05

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:14:21
User entered '78613'	System	16 Apr 2021 13:14:05

US3462244

Folder: SAE USA-US093-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:05

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
User entered 'US'	(b) (4) System	16 Apr 2021 13:14:31

US3462244

Folder: SAE USA-US093-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Apr 2021 13:14:31

US3462244

Folder: SAE USA-US093-2021-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:44:05

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
User entered '16/Apr/2021 06:14'	(b) (4) System	16 Apr 2021 13:14:31

US3462244

Folder: SAE USA-US093-2021-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:44:05

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.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:20
User entered 'I'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:14:31